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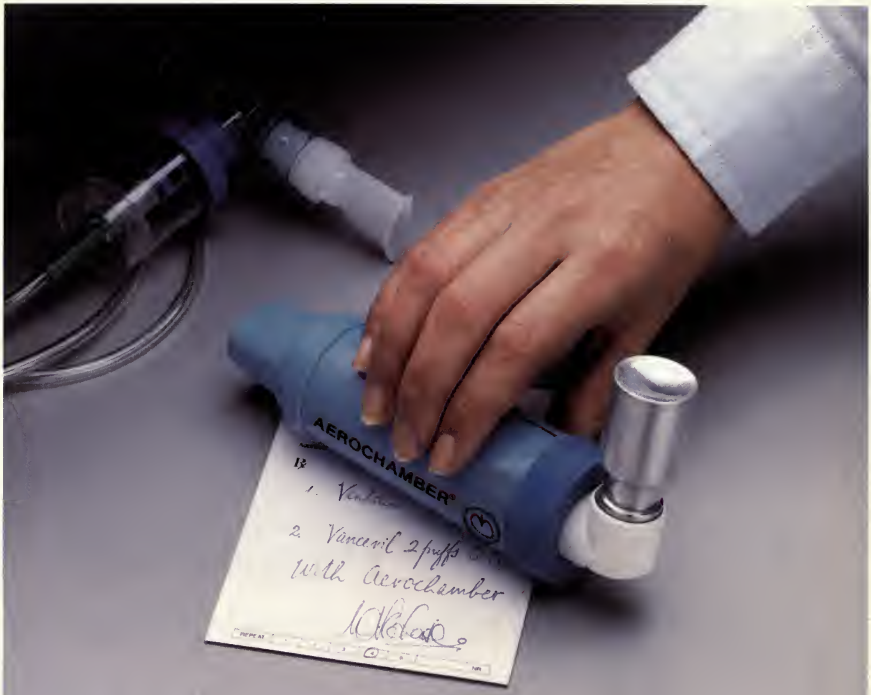

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(2) Ref. Berenberg MJ, Baigelman W, Cupples LA, Pearce L. Comparison of metered dose inhaler attached to an AEROCHAMBER with an updraft nebulizer for the administration of metaproterenol in hospitalized patients. Journal of Asthma, 22: 87-92 (1985)

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Self-Extubations: A 12-Month Experience—DP Coppolo, JJ May. Chest 1990;98:165.

Unplanned removal of an endotracheal airway tube by a patient represents a potentially life-threatening incident. Prospective monitoring of all intubated adult ICU patients for one year revealed that 12 of 112 extubated themselves (overall incidence 11%). Comparison of self-extubated (SXT) patients with the non-self-extubated (NXT) group disclosed no risk factors for this occurrence. The proportion of patient-hours was similar when both groups were examined for tube size, tube site, ventilation mode, and ventilator type. The mean hours of intubation was lower in the SXT group. Sixty-nine percent of unplanned extubations were deliberate; the majority of these occurred despite use of sedation and restraints. No death resulted from these events. The complication (and reintubation) rate in the SXT group was 31%. The reintubation rate in deliberate extubations was 11%. Self-extubation is a common occurrence that, despite obvious hazards, often is tolerated well by adults.

Continuous Enteral Feeding: A Major Cause of Pneumonia among Ventilated Intensive Care Unit Patients—S Jacobs, RWS Chang, B Lee, FW Bartlett. JPEN 1990;14:353.

Continuous enteral feeding is widely practiced in intensive care units. We found that pneumonia developed in 54% of 24 ventilated patients on continuous enteral feeding for more than 3 days. This appeared to affect only patients with a persistently high morning (7:00 am) gastric pH, with 12 of 13 (92%) patients developing pneumonia. In 11 patients the causative organisms were cultured initially from the stomach, oropharynx, and trachea before pneumonia supervened. This effect was distinct from that found with the prophylactic use of antacids of H_2-receptor antagonists. The mortality (46%) of this group of patients was 1.6 times greater than the expected mortality predicted by the Apache II Severity of Disease Classification System.

Exposure of Children with Cystic Fibrosis To Environmental Tobacco Smoke—BK Rubin. N Engl J Med 1990;323:782.

Background: In children, passive exposure to environmental tobacco smoke has been associated with growth suppression and an increased frequency of respiratory tract infections. On the assumption that this association would be more pronounced in children with chronic pulmonary disease, we examined the growth, nutritional status, lung function, and clinical condition of children with cystic fibrosis in relation to their exposure to environmental tobacco smoke. Methods: We studied 43 children (age 6-11 y) on entry to summer camp and then again after two weeks in this smoke-free environment. Twenty-four of the children (56%) came from homes with smokers. Results: There appeared to be a dose-dependent relation between the estimate of smoke exposure (cigarettes smoked/day in the home) and overall severity of disease, as assessed by the age-adjusted rate of hospital admissions ($r = 0.58$), peak expiratory flowrate ($r = -0.39$), and measures of growth and nutrition, including weight percentile ($r = -0.37$), height percentile ($r = -0.44$), midarm circumference ($r = -0.42$), and triceps skin-fold thickness ($r = -0.31$). These effects were most evident in the girls. When only the 24 children from homes with smokers were analyzed, however, the dose-dependent relation was present only for the number of hospital admissions and for height. Among the children with good lung function ($n = 21$) or with normal weight for height ($n = 27$) at the start of camp, those who had been exposed to tobacco smoke gained significantly more weight during the two weeks of camp than did the children from smoke-free homes. These data suggest that passive exposure to tobacco smoke adversely affects the growth and health of children with cystic fibrosis, although the possibility cannot be ruled out that social, economic, or other factors determined both the smoking status of the household and the nutritional status of the children.

Relationship of Bioimpedance to Thermodilution and Echocardiographic Measurements of Cardiac Function—FG Spinale, AC Smith, FA Crawford. Crit Care Med 1990;18:414.

Bioimpedance cardiography has been suggested as a noninvasive means to monitor cardiac function. However, this method has not been compared to more conventional techniques such as echocardiography. This study compared simultaneously obtained thermodilution cardiac output and right ventricular ejection fraction (RVEF), and echocardiographic left ventricular fractional shortening (LVFS), to bioimpedance cardiac output and the maximum first derivative of the bioimpedance signal (dZ/dt_{max}) during positive inotropic simulation and preload reduction. Eight pigs were instrumented with a rapid response thermistor (positioned in the pulmonary artery) and bioimpedance electrodes. Simultaneous thermodilution, echocardiographic, and bioimpedance measurements were performed at baseline and after 5, 10, and 15 min of isoproterenol infusion (0.5 μg/kg · min). In six pigs, measurements were also performed after balloon occlusion of the inferior vena cava. A

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significant correlation was observed between LVFS and dZ/dt_{max} ($r = 0.88$, $n = 35$) over all time points. Thermodilution and bioimpedance cardiac output were in close agreement ($r = 0.92$, $n = 35$). However, bioimpedance overestimated cardiac output in the very low and high output states. The mean difference between thermodilution and bioimpedance cardiac outputs was -0.02 ± 0.37 L/min. There was a positive relationship between RVEF and dZ/dt_{max} ($r = 0.54$, $n = 35$). In summary, bioimpedance was significantly correlated with thermodilution cardiac output over a wide hemodynamic range. The peak first derivative of the bioimpedance signal dZ/dt_{max} may provide a noninvasive index of ventricular pump performance. Further studies are required to evaluate the diagnostic value of bioimpedance cardiography in the clinical setting.

Pulmonary Function Measures in Healthy Infants: Variability and Size Correction—JP Hanrahan, IB Tager, RG Castile, MR Segal, ST Weiss, FE Speizer. Am Rev Respir Dis 1990;141:1127.

We conducted 151 tests of pulmonary function (PF) on 72 healthy infants younger than 2 years of age using partial expiratory flow volume (PEFV) maneuvers and helium dilution determination of FRC. After tests were grouped into four strata based on postconception (PC) age, variability and sex differences in level of PF were examined. No significant sex differences were found for any PF measure in any age stratum, even when somatic size was controlled by length correction. Forced expiratory flow measures, however, tended to be greater in girls than in boys in the youngest infants. Flow measures demonstrated greater between-subject variability than did volumes, and variability was greatest in the youngest infants. Within-subject variability also was more pronounced for flow measures, particularly in infants younger than 50 PC weeks of age. Across the age range of infants studied, all PF measures were related linearly to somatic size as measured by either length, weight, or chest circumference. Length offered the best individual size correction of the three size parameters studied. Linear regression of PF parameters versus length demonstrated FRC to increase at 5.39 mL/cm over this age range, whereas flow at FRC increased by 9.67 mL/s/cm. We conclude that the variability of infant PF measures is greatest in early infancy, that measures of forced expiratory flow are more variable than volume measures, and that sex differences in infant PF do not appear significant. Length is related linearly to PF measures and offers reasonable size correction for healthy infants younger than 18 months of age.

Hidden Mortality Rate Associated with Extracorporeal Membrane Oxygenation—RF Boedy, CG Howell, WP Kanto Jr. J Pediatr 1990;117:462.

We reviewed the outcome of all infants referred to, and accepted in, our extracorporeal membrane oxygenation (ECMO) program during a 52-month period. One hundred sixty-seven referrals, representing 158 infants and 9 mothers who had not yet delivered their infants, were accepted. Eighteen infants (11.3% of all neonates transported) died before leaving the referring hospital, during transport, or shortly after admission to our unit. Contraindications to ECMO excluded 17 (10.1%) of the 167 referrals. Sixty-two infants (37.1%) initially did not meet ECMO criteria. Two died before ECMO could be started. Sixty-eight infants (40.7%) were given ECMO therapy, and 11 died (16.1%). Nine mothers were referred because of fetal conditions that might require ECMO; of these infants, 2 died during delivery and 3 had contraindications to the use of ECMO. The 4 remaining infants were given ECMO therapy; 3 survived. The overall mortality rate was 27.5% (46/167); 18 of the 46 deaths (39.1%) were associated with transfer. The mortality rate associated with congenital diaphragmatic hernia was 63.6%. We recommend early transport of infants with this type of hernia during the postoperative 'honeymoon' or during in utero transport with delivery at an ECMO center. We also recommend that infants with meconium aspiration syndrome be transported to an ECMO center when an oxygenation index of 25 is reached. The mortality rate associated with transport needs to be considered in evaluating ECMO programs. Earlier, expedited transfers may increase the survival rate.

A New Method for Measurement of Airway Occlusion Pressure—M Brenner, DS Mukai, JE Russell, EM Spiritus, AF Wilson. Chest 1990;98:421.

Airway occlusion pressure correlates with central respiratory drive. The airway occlusion pressure $P_{0.1}$ may be an excellent predictor of the ability of patients with obstructive lung disease to wean from mechanical ventilation. We describe a new method for measuring $P_{0.1}$ using digitized signals generated from standard respiratory equipment and a computer program to automatically determine $P_{0.1}$ values. The accuracy of this new method was tested by comparison with standard analog recorder methods using a mechanical lung model, in ventilated patients in an intensive care unit, and in normal volunteers. In all settings, excellent correlation was obtained between $P_{0.1}$ measurements by the digital Servo and standard analog methods ($r = 0.99$). This new method permits accurate and automatic determination of $P_{0.1}$ in ventilated patients using standard respiratory equipment. The rapid response and ease of use of this method should enable evaluation

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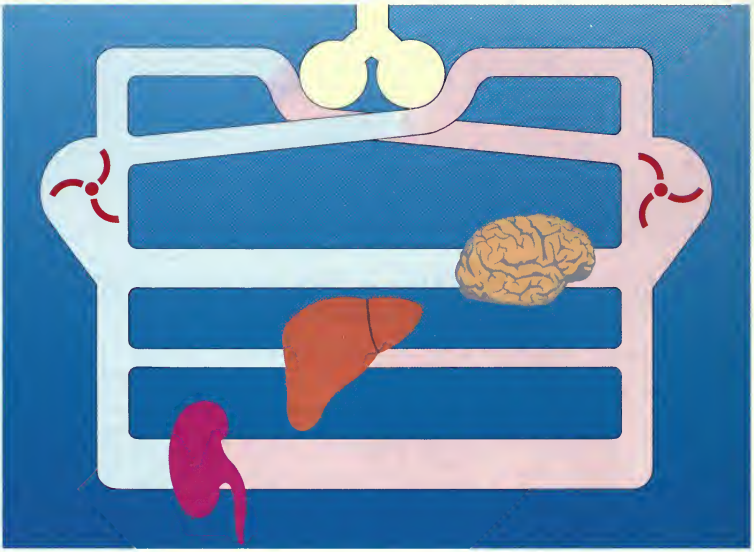

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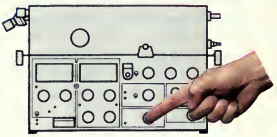

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Impact of Treatment Guidelines on Use of Ribavirin—KD Herzog, SS Long, M McGuigan, MC Fisher, A Deforest. Am J Dis Child 1990;144:1001.

During the 1987 through 1988 seasonal peak of respiratory syncytial virus (RSV), 177 courses of ribavirin were administered at St Christopher's Hospital for Children, a tertiary care medical center in Philadelphia, Pennsylvania. Charts were reviewed on 100 treated patients with proved or suspected RSV disease to determine adherence to American Academy of Pediatrics treatment guidelines. Ninety-four percent fulfilled criteria for the risk of significant morbidity: cardiac, pulmonary, or immunodeficiency conditions (38%); an age of 6 weeks or younger (35%); or severe illness (21%). Severe illness was defined as hypoxemia, hypercapnia, or marked tachypnea. Of those treated because of underlying conditions, 71% had RSV documented, as did 71% of patients aged 6 weeks or younger and 81% of patients with severe disease. A study of 80 consecutive patients who were hospitalized with illness compatible with RSV infection revealed that 56% of patients were treated with ribavirin. Adherence to guidelines led to ribavirin use in half of the hospitalized patients with suspected RSV infection. The majority of these patients received therapy because of underlying conditions or very young age.

Aerosolized Pentamidine for Prophylaxis against *Pneumocystis carinii* Pneumonia—GS Leoung, DW Feigal Jr, AB Montgomery, et al. N Engl J Med 1990;323:769.

Background and Methods: ***Pneumocystis carinii*** pneumonia (PCP) is the most frequent life-threatening opportunistic infection associated with human immunodeficiency virus (HIV) infection. To assess the possible value of aerosolized-pentamindine prophylaxis in different doses, a controlled clinical trial was begun in 1987 with 408 subjects at 12 treatment centers. The participants were randomly assigned to receive 30 mg of pentamidine every 2 weeks, 150 mg every 2 weeks, or 300 mg every 4 weeks. Results: 18 months after randomization, the subjects in the 300-mg arm had had 8 confirmed episodes of PCP while receiving treatment, as compared with 22 in the 30-mg arm ($p = 0.0008$). The 150-mg arm had intermediate results but ones not significantly different from those of the 300-mg arm. Participants with previous episodes of PCP and CD4-cell counts less than 200/mm^3 were at the highest risk for PCP. Conclusions: Aerosolized pentamidine was effective for prophylaxis against PCP in patients infected with HIV, according to the dose and schedule of administration. It and zidovudine were well tolerated together and had independent prophylactic benefits.

Laryngeal Mask Airway and Tracheal Tube Insertion by Unskilled Personnel—PRF Davies, SQM Tighe, GL Greenslade, GH Evans. Lancet 1990;336:977.

After a short training programme, 11 naval medical trainees inserted a laryngeal mask airway (LMA) and a tracheal tube (ETT) in random order in a total of 110 anaesthetised patients. They were allowed 40 seconds for each attempt. Success was defined as the detection of expired carbon dioxide within 40 seconds of Guedel airway removal that subsequently rose to an end-tidal value of at least 4 kPa, together with satisfactory lung expansion and ventilation, without other airway intervention by the anaesthetist. 104 LMA insertions were successful compared with 56 of ETTs ($p < 0.01$). All first attempts at LMA insertion were successful, whereas satisfactory ETT placement was progressive. Insertion was also quicker with the LMA (20 seconds) than with the ETT (35 seconds) ($p < 0.01$). Further studies are indicated to assess the value of the LMA in emergencies.

Assessing Precision and Accuracy in Blood Gas Proficiency Testing—JE Hansen, R Casaburi, RO Crapo, RL Jensen. Am Rev Respir Dis 1990; 141:1190.

Blood gas proficiency testing has focused on assessing the accuracy of measurement of each analyte (pH, P_{CO_2}, and P_{O_2}) independently of each other. Recently, the American Thoracic Society-California Thoracic Society Blood Gas Proficiency Testing Survey distributed the same lot of ampules of proficiency testing material (a buffered fluorocarbon-containing emulsion) on three occasions within a 1-year period, allowing us to assess the precision (reproducibility) of measurement of each analyte. Comparing 580 instruments of 13 models, we found that the precision of measurement of each analyte was positively correlated with the precision of measurement of each other analyte, and the correlation of precision between models was much stronger than precision between the individual instruments. We also found correlation of precision of each analyte with two targets for accuracy: (1) the all-instrument mean and (2) the model-specific means. Correlations were higher with the model-specific means. These findings suggest: (1) that features unique to design of each model are important in the precision of measurement of these ampules, and (2) that it would be informative to include measurements of precision with linked and cumulative ratings of analyte accuracy in proficiency testing rating systems.

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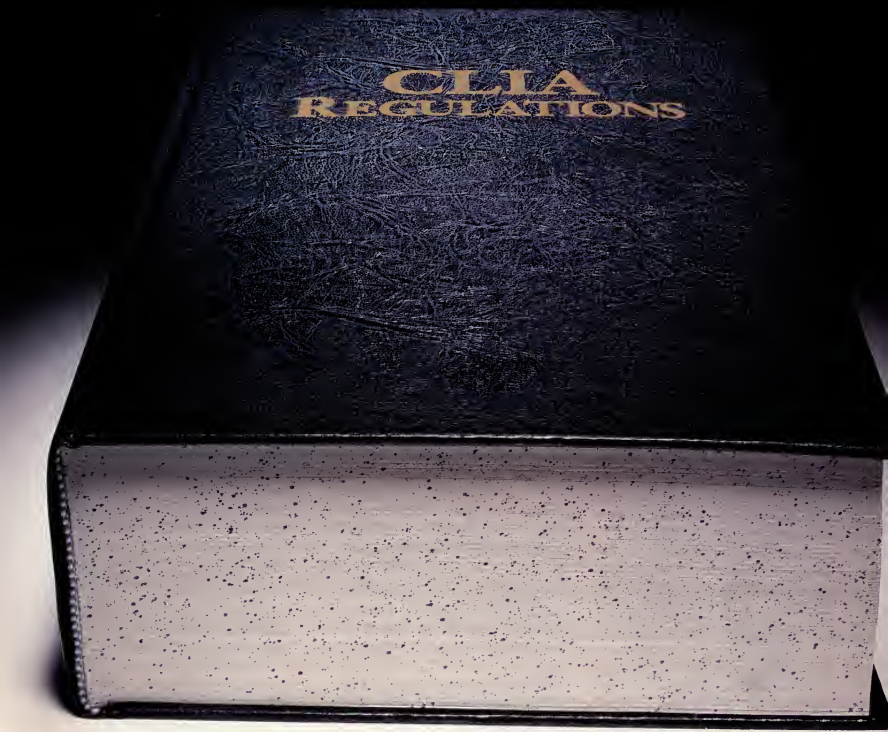

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Radiologic Diagnosis of Epiglottitis: Objective Criteria for All Ages—SG Rothrock, GA Pignatiello, RM Howard. Ann Emerg Med 1990;19:978.

A retrospective study was undertaken to define objective radiologic parameters in diagnosing epiglottitis on soft-tissue lateral neck radiographic studies. Ratios of soft-tissue structures in 31 patients aged 7 months to 61 years with epiglottitis were compared with those of age- and sex-matched controls with croup, pharyngitis, and dysphagia. The ratios of epiglottic width to third cervical vertebral body width (EW/C3W) of more than 0.5, of aryepiglottic width to third cervical vertebral body width (AEW/C3W) of more than 0.35, and of epiglottic width to epiglottic height (EW/EH) of 0.6 or more were all found to be 100% sensitive and specific in differentiating between adult patients with and without epiglottitis. In children, EW/C3W, AEW/C3W, and EW/EH ratios of more than 0.5, of more than 0.35, and of 0.6 or more, respectively, were found to be 100% sensitive in detecting epiglottitis with specificities of 87%, 96%, and 87%, respectively. These preliminary results suggest that EW/C3W, EW/EH, and AEW/C3W ratios of more than 0.5, of 0.6 or more, and of more than 0.35, respectively, may be useful in the radiologic diagnosis of epiglottitis in patients of all ages.

Hyperbaric Oxygen Use in Neonates—RL Vazquez, RC Spahr. Am J Dis Child 1990;144:1022.

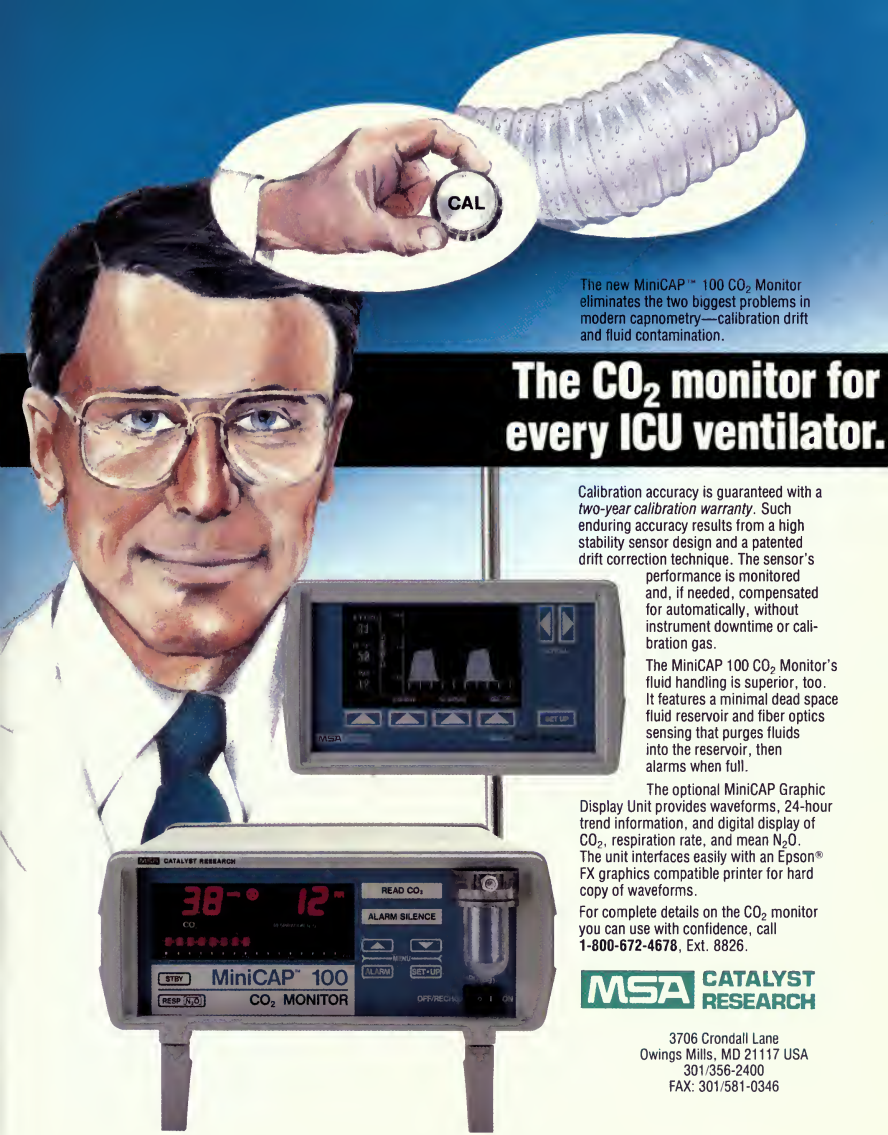
We report the use of hyperbaric oxygen in four neonates with delayed wound healing. Three presented with cyanotic congenital heart disease and had wounds associated with surgical procedures; the fourth had a nonhealing wound as a result of a complication of an umbilical-artery catheter. All were treated in a hyperbaric chamber with 100% oxygen at 2 atmospheres absolute. All wounds healed after institution of hyperbaric therapy. There was no evidence of serious side effects in any patient. These observations suggest, but do not prove, the efficacy of hyperbaric oxygen therapy for neonates with delayed wound healing.

The Ventilator-Assisted Individuals Study—AI Goldberg, D Frownfelter. Chest 1990;98:428.

A paucity of reliable data exists concerning ventilator-assisted individuals (VAIs) for program planning. The Chicago Lung Association, with funding from Blue Cross/Blue Shield of Illinois, conducted a community action project to determine the magnitude of the issues in Illinois. The purposes of the VAI Study were to ascertain needs and resources, generate recommendations, and recruit community involvement. The survey identified 453 VAIs: 145 in hospitals, 105 in extended-care facilities, and 203 at home. A majority (62%) of hospitals provided services to VAIs; many more would with proper reimbursement incentives. Only 60% of hospitals serving VAIs had active discharge teams; discharge was accomplished by a variety of mechanisms and personnel. Monthly hospital charges averaged $22,190 with a range from $10,020 to $66,750 depending on the location of the patient. Most reimbursement was public; private funding was fragmented. Major discharge barriers were inadequate payment for community-based services, limited community resources, constrained consumer's finances, and lack of access to information. Recommendations for future community action included establishing a technology transfer system, home care case management, an integrated management system, a documentation center, and trials and demonstrations prior to program and policy development.

Lung Cancer and Exposure to Tobacco Smoke in the Household—DT Janerich, WD Thompson, LR Varela. N Engl J Med 1990;323:632.

Background: The relation between passive smoking and lung cancer is of great public health importance. Some previous studies have suggested that exposure to environmental tobacco smoke in the household can cause lung cancer, but others have found no effect. Smoking by the spouse has been the most commonly used measure of this exposure. In order to determine whether lung cancer is associated with exposure to tobacco smoke within the household, we conducted a population-based case-control study of 191 patients with histologically confirmed primary lung cancer who had never smoked and an equal number of persons without lung cancer who had never smoked. Lifetime residential histories including information on exposure to environmental tobacco smoke were compiled and analyzed. Exposure was measured in terms of 'smoker-years,' determined by multiplying the number of years in each residence by the number of smokers in the household. Results: Household exposure to $\geqslant$ 25 smoker-years during childhood and adolescence doubled the risk of lung cancer (odds ratio 2.07; 95% confidence interval, 1.16 to 3.68). Approximately 15% of the control subjects who had never smoked reported this level of exposure. Household exposure of $<$ 25 smoker-years during childhood and adolescence did not increase the risk of lung cancer. Exposure to a spouse's smoking, which constituted less than one third of total household exposure on average, was not associated with an increase in risk. Conclusions: The possibility of recall bias and other methodologic problems may influence the results of case-control studies of environmental tobacco smoke. Nonetheless, our findings regarding exposure during early life suggest that approximately 17% of lung cancers among nonsmokers can be



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attributed to high levels of exposure to cigarette smoke during childhood and adolescence.

Effects of Spontaneous and Simulated Gastroesophageal Reflux on Sleeping Asthmatics—WC Tan, RJ Martin, R Pandey, RD Ballard. Am Rev Respir Dis 1990;141:1394.

We examined the effect of intraesophageal acid (either spontaneous gastroesophageal reflux or infused) on airflow resistance in 15 sleeping asthmatic subjects. We observed no significant acute or sustained changes in airflow resistance relative to periods of intraesophageal acid. Overnight changes in spirometry and lower airway resistance also demonstrated similar nocturnal worsening of bronchoconstriction despite the occurrence of spontaneous or simulated gastroesophageal reflux. The presence or absence of clinical evidence of esophagitis (Bernstein test response) did not alter the observed lack of response to intraesophageal acid. We conclude that gastroesophageal reflux contributes little to the nocturnal worsening of asthma.

Influence of Sleep on Lung Volume in Asthmatic Patients and Normal Subjects—RD Ballard, CG Irvin, RJ Martin, J Pak, R Pandey, DP White. J Appl Physiol 1990;68:2034.

To assess the effect of sleep on functional residual capacity (FRC) in normal subjects and asthmatic patients, 10 adult subjects (5 asthmatic patients with nocturnal worsening, 5 normal controls) were monitored overnight in a horizontal volume-displacement body plethysmograph. With the use of a single inspiratory occlusion technique, we determined that when supine and awake, asthmatic patients were hyperinflated relative to normal controls (FRC = 3.46 ± 0.18 and 2.95 ± 0.13 L, respectively; $p < 0.05$). During sleep FRC decreased in both groups, but the decrease was significantly greater in asthmatic patients such that during rapid-eye-movement (REM) sleep FRC was equivalent between the asthmatic and normal groups (FRC = 2.46 ± 0.23 and 2.45 ± 0.09 L, respectively). Specific pulmonary conductance decreased progressively and significantly in the asthmatic patients during the night, falling from 0.047 ± 0.007 to 0.018 ± 0.002 cm $H_2O^{-1} \cdot s^{-1}$ ($p < 0.01$). There was a significant linear relationship through the night between FRC and pulmonary conductance in only two of the five asthmatic patients ($r = 0.55$ and 0.65, respectively). We conclude that (1) FRC falls during sleep in both normal subjects and asthmatic patients, (2) the hyperinflation observed in awake asthmatic patients is diminished during non-REM sleep and eliminated during REM sleep, and (3) sleep-associated reductions in FRC may contribute to but do not account for all the nocturnal increase in airflow resistance observed in asthmatic patients with nocturnal worsening.

Oxygenation Index in Patients with Meconium Aspiration: Conventional and Extracorporeal Membrane Oxygenation Therapy—M Durand, JR Snyder, E Gangitano, PYK Wu. Crit Care Med 1990;18:373.

The use of the alveolar-arterial oxygen difference $P_{(A-a)O_2}$ and the oxygenation index (mean airway pressure [$\bar{P}$ aw] $F_{IO_2} \times 100/P_{aO_2}$) have been proposed for selecting infants who will require extracorporeal membrane oxygenation (ECMO) therapy. However, the use of the oxygenation index (OI) in conjunction with $\bar{P}$aw in an exclusive population of patients with meconium aspiration syndrome (MAS) has not been reported. Fourteen patients born in our facility and managed with conventional therapy and five infants treated with ECMO were enrolled in the study. All patients had clinical and x-ray evidence of MAS. Infants who received conventional treatment required mechanical ventilation $\pm$ 48 h, F_{IO_2} 1.0, and were under the care and supervision of one neonatologist. Management was directed to minimize barotrauma by avoidance of routine hyperventilation, use of lower $\bar{P}$aw, and sufficient expiratory time. One patient died before ECMO and 13 infants survived. Six survivors had an OI > 25 (three had an OI > 40), six had a Paw ≥ 12 cm H_2O (12 to 15 cm H_2O in five infants), and six patients had a $P_{(A-a)O_2} \geq 610$ torr. One surviving infant was transferred for ECMO therapy (OI 67, $\bar{P}$aw 20 cm H_2O). The five patients treated with ECMO survived (OI 48 to 92, $\bar{P}$aw 20 to 29.5 cm H_2O, $P_{(A-a)O_2}$ 627 to 650 torr). One patient in each group developed chronic lung disease with evidence of resting tachypnea. Our findings indicate that an OI > 40 in association with a $\bar{P}$aw ≥ 20 cm H_2O may be helpful in predicting which infants with MAS need ECMO, whereas patients requiring a $\bar{P}$aw ≤ 15 cm H_2O can be managed with conventional therapy. An OI ≥ 25 but < 40 is not associated with high mortality in these patients. The predictive value of $\bar{P}$aw of 16 to 20 cm H_2O and the duration of an OI > 40 in patients with MAS need further investigation.

Call For 1991 Open Forum Abstracts

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NOW, THERE'S
MORE THAN HOPE
FOR INFANTS WITH
RESPIRATORY
DISTRESS
SYNDROME
Baby's Breath
Gypsophila paniculata

New, protein-free synthetic lung surfactant that's as easy to use as it is effective

Exosurf® NEONATAL™

(Colfosceril Palmitate, Cetyl Alcohol, Tyloxapol) For Intratracheal Suspension

At last, there's more than hope for infants with respiratory distress syndrome (RDS). Clinical trials have shown that protein-free synthetic EXOSURF Neonatal dramatically reduced neonatal morbidity and mortality. In addition to being effective in both prophylactic and rescue use, EXOSURF Neonatal was well tolerated.

Widely studied

To date, in excess of 2,600 premature infants have received EXOSURF Neonatal in controlled clinical trials involving more than 4,400 infants in North America. In addition, 10,000 infants in more than 400 hospitals have received EXOSURF Neonatal under a treatment IND.

Effective in infants at risk of developing RDS

A single, prophylactic dose of EXOSURF Neonatal given immediately following birth reduced death from RDS by 50% and one-year mortality by 33% in neonates weighing 700 to 1100 grams. Two additional prophylactic doses of EXOSURF Neonatal reduced one-year mortality by an additional 30%. EXOSURF Neonatal reduced the severity of RDS and the incidence of lung rupture in these premature infants.

Effective in infants with RDS

In infants weighing 700 to 1350 grams, EXOSURF Neonatal rescue treatment initiated within 24 hours of birth, reduced death from RDS by 66% and one-year mortality by 44%. Survival to day 28 without bronchopulmonary dysplasia was increased significantly. Pneumothorax, pulmonary interstitial emphysema, and overall pulmonary air leaks were significantly reduced. Similarly beneficial effects were also observed in infants with RDS weighing >1350 grams, and chronic lung disease was significantly reduced.

Impressive safety profile

In individual controlled clinical trials, adverse events were comparable to those of placebo, with the exception of apnea. Infants receiving EXOSURF Neonatal required less ventilatory support, possibly contributing to an increased incidence of apnea. In both placebo and treated infants, apnea proved to be a marker for reduced pulmonary air leak and improved survival.

In the treatment IND experience of over 10,000 infants, the reported incidence of pulmonary bleeding was 4%. It appears to be related to improvements in pulmonary function in infants whose ductus arteriosus remains patent. This condition may be prevented by early and aggressive diagnosis and treatment (unless contraindicated) of patent ductus arteriosus during the first two days of life (while the ductus arteriosus is often clinically silent). Additionally, a low incidence (3/1,000) of mucous plugging of the endotracheal tube was observed.

Please see full prescribing information on last pages of this advertisement.

Exosurf® NEONATAL™
(Colfosceril Palmitate, Cetyl Alcohol, Tyloxapol) For Intratracheal Suspension

Easy to store

- EXOSURF Neonatal may be stored at room temperature (15° to 30°C [59° to 86°F]).
- Reconstituted suspension may be maintained refrigerated or at room temperature (2° to 30°C [36° to 86°F]) for up to 12 hours.

Easy to use

- Key items needed for EXOSURF Neonatal administration are supplied in one carton: one 10 mL vial of EXOSURF Neonatal, one 10 mL vial of Sterile Water for Injection, and five endotracheal tube adapters (2.5 mm, 3.0 mm, 3.5 mm, 4.0 mm, and 4.5 mm).

Easy to administer

- Each EXOSURF Neonatal dose is administered in two 2.5 mL/kg half-doses.
- EXOSURF Neonatal is administered via a sideport on a special endotracheal tube adapter (supplied with EXOSURF Neonatal) without interrupting mechanical ventilation.

Easy on the infant

- To assist the distribution of EXOSURF Neonatal in the lungs, the infant is simply turned from midline position to the right after the first half-dose and from midline position to the left after the second half-dose.

A complimentary videotape on reconstitution and administration of EXOSURF Neonatal is available from your Burroughs Wellcome Co. representative.

Please see full prescribing information on last pages of this advertisement. Call your Burroughs Wellcome Co. professional representative for further information.

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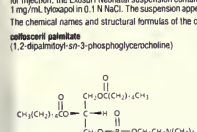
EXOSURF® (COLFOSCERIL PALMITATE, CETYL ALCOHOL, TYLOXAPOL)
Neonatal For Intratracheal Suspension

DESCRIPTION: Exosurf Neonatal for Intratracheal Suspension is a protein-free synthetic lung surfactant stored under vacuum as a sterile lyophilized powder. Exosurf Neonatal is reconstituted with preservative-free Sterile Water for Injection prior to administration by intratracheal instillation. Each 10 mL vial contains 108 mg colfosceril palmitate, commonly known as dipalmitoylphosphatidylcholine (DPPC), formulated with 12 mg cetyl alcohol, 8 mg tyloxapol, and 47 mg sodium chloride. Sodium hydroxide or hydrochloric acid may have been added to adjust pH. When reconstituted with 8 mL Sterile Water for Injection, the Exosurf Neonatal suspension contains 13.5 mg/mL colfosceril palmitate, 1.5 mg/mL cetyl alcohol, and 1 mg/mL tyloxapol in 0.1 N NaCl. The suspension appears milky white with a pH of 5 to 7 and an osmolality of 185 mOsm/L.

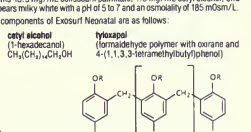
The chemical names and structural formulas of the components of Exosurf Neonatal are as follows:

colfosceril palmitate
(1,2-dipalmitoyl-*sn*-3-phosphoglycerocholine)



cetyl alcohol
(1-hexadecanol)
$CH_3(CH_2)_{14}CH_2OH$

tyloxapol
(formaldehyde polymer with oxirane and 4-(1,1,3,3-tetramethylbutyl)phenol)



[R is $CH_2CH_2O(CH_2CH_2O)_mCH_2CH_2OH$; m is 5 to 8; n is not more than 5]

CLINICAL PHARMACOLOGY: Surfactant deficiency is an important factor in the development of the neonatal respiratory distress syndrome (RDS). Thus, surfactant replacement therapy early in the course of RDS should ameliorate the disease and improve symptoms. Natural surfactant, a combination of lipids and apoproteins, exhibits not only surface tension reducing properties (conferred by the lipids), but also rapid spreading and adsorption (conferred by the apoproteins). The major fraction of the lipid component of natural surfactant is DPPC, which comprises up to 70% of natural surfactant by weight.

Although DPPC reduces surface tension, DPPC alone is ineffective in RDS because DPPC spreads and adsorbs poorly in Exosurf Neonatal, which is protein free, cetyl alcohol acts as the spreading agent for the DPPC on the air-liquid interface. Tyloxapol, a polymeric long-chain repeating alcohol, is a nonionic surfactant which acts to disperse both DPPC and cetyl alcohol. Sodium chloride is added to adjust osmolality.

Pharmacokinetics: Exosurf Neonatal is administered directly into the trachea. Human pharmacokinetic studies of the absorption, biotransformation, and excretion of the components of Exosurf Neonatal have not been performed. Nonclinical studies, however, have shown that DPPC can be absorbed from the alveolus into lung tissue where it can be catabolized extensively and reutilized for further phospholipid synthesis and secretion. In the developing rabbit, 90% of alveolar phospholipids are recycled. In premature rabbits, the alveolar half-life of intratracheally administered ^{14}-labeled phosphatidylcholine is approximately 12 hours.

Animal Studies: In animal models of RDS, treatment with Exosurf Neonatal significantly improved lung volume, compliance and gas exchange in premature rabbits and lambs. The amount and distribution of lung water were not affected by Exosurf Neonatal treatment of premature rabbit pups. The extent of lung injury in premature rabbit pups undergoing mechanical ventilation was reduced significantly by Exosurf Neonatal treatment. In premature lambs, neither systemic blood flow nor flow through the ductus arteriosus were affected by Exosurf Neonatal treatment. Survival was significantly better in both premature rabbits and premature lambs treated with Exosurf Neonatal.

Clinical Studies: Exosurf Neonatal has been studied in the U.S. and Canada in controlled clinical trials involving more than 4400 infants. Over 10,000 infants have received Exosurf Neonatal through an open, uncontrolled, North American study designed to provide the drug to premature infants who might benefit and to obtain additional safety information (Exosurf Neonatal Treatment IND).

Prophylactic Treatment: The efficacy of a single dose of Exosurf Neonatal in prophylactic treatment of infants at risk of developing respiratory distress syndrome (RDS) was examined in three double-blind, placebo-controlled studies, one involving 215 infants weighing 500 to 700 grams, one involving 385 infants weighing 700 to 1350 grams, and one involving 446 infants weighing 700 to 1100 grams. The infants were intubated and placed on mechanical ventilation, and received 5 mL/kg Exosurf Neonatal or placebo (air) within 30 minutes of birth.

The efficacy of one versus three doses of Exosurf Neonatal in prophylactic treatment of infants at risk of developing RDS was examined in a double-blind, placebo-controlled study of 823 infants weighing 700 to 1100 grams. The infants were intubated and placed on mechanical ventilation, and received a first 5 mL/kg dose of Exosurf Neonatal within 30 minutes. Repeat 5 mL/kg doses of Exosurf Neonatal or placebo (air) were given to all infants who remained on mechanical ventilation at approximately 12 and 24 hours of age. An initial analysis of 716 infants is available.

The major efficacy parameters from these studies are presented in Table 1.

Table 1 — **Efficacy Assessments—Prophylactic Treatment**

Number of Doses: / Birth Weight Range:	Single Dose 500 to 700 grams		Single Dose 700 to 1350 grams		Single Dose 700 to 1100 grams		One Versus Three Doses 700 to 1100 grams	
Treatment Group / Number of Infants:	Placebo (Air) N = 106	EXOSURF N = 109	Placebo (Air) N = 185	EXOSURF N = 176	Placebo (Air) N = 222	EXOSURF N = 224	One EXOSURF Dose N = 356	Three EXOSURF Doses N = 360
	% of Infants		% of Infants		% of Infants		% of Infants	
Death ≤ Day 28[a]	53	50	11	6	21	15	16	9*
Death through 1 Year[a]	58	60	14	11	30	20**	17	12*
Death from RDS[b]	25	13*	4	3	10	5§	3	2
Intact Cardiopulmonary Survival[a c]	29	25	69	78*	55	68	74	78
Bronchopulmonary Dysplasia (BPD)[a d]	43	44	23	18	19	21	8	12
RDS incidence[b]	73	81	46	42	55	55	63	68

[a] "Intent-to-treat" analyses (as randomized) except for the 700 to 1350 gram, single dose study in which patients with congenital infections and anomalies were excluded

[b] "As-treated" analyses

[c] Defined by survival through 28 days of life without bronchopulmonary dysplasia

[d] Defined by a combination of clinical and radiographic criteria

* $p<0.05$ § $p=0.051$
** $p<0.01$

Rescue Treatment: The efficacy of Exosurf Neonatal in the rescue treatment of infants with RDS was examined in two double-blind, placebo-controlled studies. One study enrolled 419 infants weighing 700 to 1350 grams; the second enrolled 1237 infants weighing 1250 grams and above. In the rescue treatment studies, infants received an initial dose (5 mL/kg) of Exosurf Neonatal or placebo (air) between 2 and 24 hours of life followed by a second dose (5 mL/kg) approximately 12 hours later to infants who remained on mechanical ventilation. The major efficacy parameters from these studies are presented in Table 2.

Table 2 — **Efficacy Assessments—Rescue Treatment**

Number of Doses: / Birth Weight Range	Two Doses 700 to 1350 grams		Two Doses 1250 grams and above	
Treatment Group: / Number of Infants:	Placebo (Air) N = 213	EXOSURF N = 206	Placebo (Air) N = 623	EXOSURF N = 614
	% of Infants		% of Infants	
Death ≤ Day 28[a]	23	11***	7	4*
Death through 1 Year[a]	27	15***	9	6§
Death from RDS[b]	10	3**	3	1*
Intact Cardiopulmonary Survival[a c]	62	76**	88	93**
Bronchopulmonary Dysplasia (BPD)[a,d]	18	15	6	3*

[a] "Intent-to-treat" analyses (as randomized)

[b] "As-treated" analyses

[c] Defined by survival through 28 days of life without bronchopulmonary dysplasia

[d] Defined by a combination of clinical and radiographic criteria

* $p<0.05$ § $p=0.067$
** $p<0.01$
*** $p<0.001$

Clinical Results: In these six controlled clinical studies, infants in the Exosurf Neonatal group showed significant improvements in FiO_2 and ventilator settings which persisted for at least 7 days. Pulmonary air leaks were significantly reduced in each study. Five of these studies also showed a significant reduction in death from RDS. Further, overall mortality was reduced for all infants weighing >700 grams. The one versus three-dose prophylactic treatment study in 700 to 1100 gram infants showed a further reduction in overall mortality with two additional doses.

Safety information is presented in Tables 3 and 4 (see ADVERSE REACTIONS). Beneficial effects in the Exosurf Neonatal group were observed for some safety assessments. Various forms of pulmonary air leak and use of pancuronium were reduced in infants receiving Exosurf Neonatal in all six studies.

Follow-up data at one year adjusted age are available on 1094 of 2470 surviving infants. Growth and development of infants who received Exosurf Neonatal in this sample were comparable to infants who received placebo.

INDICATIONS AND USAGE: Exosurf Neonatal is indicated for:

1. **Prophylactic** treatment of infants with birth weights of less than 1350 grams who are at risk of developing RDS (see PRECAUTIONS),
2. **Prophylactic** treatment of infants with birth weights greater than 1350 grams who have evidence of pulmonary immaturity, and
3. **Rescue** treatment of infants who have developed RDS.

For **prophylactic** treatment, the first dose of Exosurf Neonatal should be administered as soon as possible after birth (see DOSAGE AND ADMINISTRATION: General Guidelines for Administration).

Infants considered as candidates for **rescue** treatment with Exosurf Neonatal should be on mechanical ventilation and have a diagnosis of RDS by both of the following criteria:

1. Respiratory distress not attributable to causes other than RDS, based on clinical and laboratory assessments,
2. Chest radiographic findings consistent with the diagnosis of RDS.

During the clinical development of Exosurf Neonatal, all infants who received the drug were intubated and on mechanical ventilation. For three-dose prophylactic treatment with Exosurf Neonatal, the first dose of drug was administered as soon as possible after birth and repeat doses were given at approximately 12 and 24 hours after birth if infants remained on mechanical ventilation at those times. For rescue treatment, two doses were given; one between 2 and 24 hours of life, and a second approximately 12 hours later if infants remained on mechanical ventilation. Infants who received rescue treatment with Exosurf Neonatal had a documented arterial to alveolar oxygen tension ratio (a/A) <0.22.

CONTRAINDICATIONS: There are no known contraindications to treatment with Exosurf Neonatal.

WARNINGS:

Intratracheal Administration Only: Exosurf Neonatal should be administered only by instillation into the trachea (see DOSAGE AND ADMINISTRATION).

General:

The use of Exosurf Neonatal requires expert clinical care by experienced neonatologists and other clinicians who are accomplished at neonatal intubation and ventilatory management. Adequate personnel, facilities, equipment, and medications are required to optimize perinatal outcome in premature infants.

Instillation of Exosurf Neonatal should be performed **only** by trained medical personnel experienced in airway and clinical management of unstable premature infants. Vigilant clinical attention should be given to all infants prior to, during, and after administration of Exosurf Neonatal.

Acute Effects: Exosurf Neonatal can rapidly affect oxygenation and lung compliance.

Lung Compliance: If chest expansion improves substantially after dosing, peak ventilator inspiratory pressures should be reduced immediately, without waiting for confirmation of respiratory improvement by blood gas assessment. Failure to reduce inspiratory ventilator pressures rapidly in such instances can result in lung overdistention and fatal pulmonary air leak.

Hyperoxia: If the infant becomes pink and transcutaneous oxygen saturation is in excess of 95%, FiO_2 should be reduced in small (at repeated steps) until saturation is 90 to 95%) without waiting for confirmation of elevated arterial pO_2 by blood gas assessment. Failure to reduce FiO_2 in such instances can result in hyperoxia.

Hypocarbia: If arterial or transcutaneous CO_2 measurements are <30 torr, the ventilator rate should be reduced at once. Failure to reduce ventilator rates in such instances can result in marked hypocarbia, which is known to reduce brain blood flow.

Pulmonary Hemorrhage: In the single study conducted in infants weighing <700 grams at birth, the incidence of pulmonary hemorrhage (10% vs 2% in the placebo group) was significantly increased in the Exosurf Neonatal group. None of the five studies involving infants with birth weights >700 grams showed a significant increase in pulmonary hemorrhage in the Exosurf Neonatal group. In a cross-study analysis of these five studies, pulmonary hemorrhage was reported for 1% (14/1420) of infants in the placebo group and 2% (27/1411) of infants in the Exosurf Neonatal group. Fatal pulmonary hemorrhage occurred in three infants; two in the Exosurf Neonatal group and one in the placebo group. Mortality from all causes among infants who developed pulmonary hemorrhage was 43% in the placebo group and 37% in the Exosurf Neonatal group.

Pulmonary hemorrhage in both Exosurf Neonatal and placebo infants was more frequent in infants who were younger, smaller, male, or who had a patent ductus arteriosus. Pulmonary hemorrhage typically occurred in the first 2 days of life in both treatment groups.

In more than 7700 infants in the open, uncontrolled study, pulmonary hemorrhage was reported in 4%, but fatal pulmonary hemorrhage was reported rarely (0.4%).

In the controlled clinical studies, Exosurf Neonatal treated infants who received steroids more than 24 hours prior to delivery or indomethacin postnatally had a lower rate of pulmonary hemorrhage than other Exosurf Neonatal treated infants. Attention should be paid to early and aggressive diagnosis and treatment (unless contraindicated) of patent ductus arteriosus during the first 2 days of life (while the ductus arteriosus is often clinically silent). Other potentially protective measures include attempting to decrease FiO_2 preferentially over ventilator pressures during the first 24 to 48 hours after dosing, and attempting to decrease PEEP minimally for at least 48 hours after dosing.

Mucous Plugs: Infants whose ventilation becomes markedly impaired during or shortly after dosing may have mucous plugging of the endotracheal tube, particularly if pulmonary secretions were prominent prior to drug administration. Suctioning of all infants prior to dosing may lessen the chance of mucous plugs obstructing the endotracheal tube. If endotracheal tube obstruction from such plugs is suspected, and suctioning is unsuccessful in removing the obstruction, the blocked endotracheal tube should be replaced immediately

PRECAUTIONS:

General: In the controlled clinical studies, infants known prenatally or postnatally to have major congenital anomalies, or who were suspected of having congenital infection, were excluded from entry. However, these disorders cannot be recognized early in life in all cases, and a few infants with these conditions were entered. The benefits of Exosurf Neonatal in the affected infants who received drug appeared to be similar to the benefits observed in infants without anomalies or occult infection.

Prophylactic Treatment–Infants <700 Grams: In infants weighing 500 to 700 grams, a single prophylactic dose of Exosurf Neonatal significantly: improved FiO_2 and ventilator settings, reduced pneumothorax, and reduced death from RDS, but increased pulmonary hemorrhage (see WARNINGS). Overall mortality did not differ significantly between the placebo and Exosurf Neonatal groups (see Table 1). Data on multiple doses in infants in this weight class are not yet available. Accordingly, clinicians should carefully evaluate the potential risks and benefits of Exosurf Neonatal administration in these infants.

Rescue Treatment–Number of Dose: A small number of infants with RDS have received more than two doses of Exosurf Neonatal as rescue treatment. Definitive data on the safety and efficacy of these additional doses are not available

Carcinogenesis, Mutagenesis, Impairment of Fertility: Exosurf Neonatal at concentrations up to 10,000 µg/plate was not mutagenic in the Ames Salmonella assay

Long-term studies have not been performed in animals to evaluate the carcinogenic potential of Exosurf Neonatal

The effects of Exosurf Neonatal on fertility have not been studied

ADVERSE REACTIONS:

General: Premature birth is associated with a high incidence of morbidity and mortality. Despite significant reductions in overall mortality associated with Exosurf Neonatal, some infants who received Exosurf Neonatal developed severe complications and either survived with permanent handicaps or died.

In controlled clinical studies evaluating the safety and efficacy of Exosurf Neonatal, numerous safety assessments were made. In infants receiving Exosurf Neonatal, pulmonary hemorrhage, apnea and use of methylxanthines were increased. A number of other adverse events were significantly reduced in the Exosurf Neonatal group, particularly various forms of pulmonary air leak and use of pancuronium (See CLINICAL PHARMACOLOGY: Clinical Results.) Tables 3 and 4 summarize the results of the major safety evaluations from the controlled clinical studies

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Table 3 — **Safety Assessments[a]—Prophylactic Treatment**

Number of Doses: Birth Weight Range:	Single Dose 500 to 700 grams		Single Dose 700 to 1350 grams		Single Dose 700 to 1100 grams		One Versus Three Doses 700 to 1100 grams	
Treatment Group: Number of Infants:	Placebo (Air) N=108	EXOSURF N=107	Placebo (Air) N=193	EXOSURF N=192	Placebo (Air) N=222	EXOSURF N=224	One EXOSURF Dose N=356	Three EXOSURF Doses N=360
	% of Infants		% of Infants		% of Infants		% of Infants	
Intraventricular Hemorrhage (IVH)								
Overall	51	57	31	27	36	36	38	35
Severe IVH	26	25	10	8	13	14	9	9
Pulmonary Air Leak (PAL)								
Overall	52	48	16	11	32	25	29	27
Pneumothorax	23	10*	5	6	19	11*	14	12
Pneumopericardium	1	4	2	0	<1	1	1	1
Pneumomediastinum	2	1	2	3	7	1**	3	2
Pulmonary interstitial Emphysema	43	44	13	7*	26	20	23	22
Death from PAL	4	6	<1	<1	2	1	2	1
Patent Ductus Arteriosus	49	53	66	70	50	55	59	57
Necrotizing Enterocolitis	2	4	11	13	3	4	6	2*
Pulmonary Hemorrhage	2	10**	2	4	1	4	4	6
Congenital Pneumonia	4	4	2	4	2	2	1	1
Nosocomial Pneumonia	10	10	2	4	4	7	14	15
Non-Pulmonary Infections	33	35	34	39	28	29	35	34
Sepsis	30	34	30	34	23	24	30	27
Death From Sepsis	4	4	3	3	1	2	3	2
Meningitis	4	6	3	1	2	3	1	2
Other Infections	7	4	5	3	10	10	11	11
Major Anomalies	3	1	2	4	7	4	4	4
Hypotension	70	77	52	47	59	62	54	50
Hyperbilirubinemia	22	21	63	61	27	31	20	21
Exchange Transfusion	4	3	1	2	2	2	3	1
Thrombocytopenia[b]	21	25	not available		9	8	12	10
Persistent Fetal Circulation	0	1	1	1	0	2*	1	<1
Seizures	11	8	2	2	11	9	6	5
Apnea	34	33	76	73	55	65*	62	66
Drug Therapy								
Antibiotics	96	99	98	96	98	99	>99	99
Diuretics	55	60	39	37	59	63	64	65
Anticonvulsants	14	18	23	24	20	16	9	8
Inotropes	46	40	20	20	26	20	28	27
Sedatives	62	71	65	64	63	57	52	52
Pancuronium	19	11	22	14*	19	13*	15	11
Methylxanthines	38	43	77	77	61	72*	75	82*

[a] All parameters were examined with "as-treated" analyses. * p<0.05
[b] Thrombocytopenia requiring platelet transfusion. ** p<0.01

Table 4 — **Safety Assessments[a]—Rescue Treatment**

Number of Doses: Birth Weight Range:	Two Doses 700 to 1350 grams		Two Doses 1250 grams and above	
Treatment Group: Number of Infants:	Placebo (Air) N=213	EXOSURF N=206	Placebo (Air) N=622	EXOSURF N=615
	% of Infants		% of Infants	
Intraventricular Hemorrhage (IVH)				
Overall	48	52	23	18*
Severe IVH	13	9	5	4
Pulmonary Air Leak (PAL)				
Overall	54	34***	30	18***
Pneumothorax	29	20*	20	10***
Pneumopericardium	4	1	1	2
Pneumomediastinum	8	4	5	2**
Pulmonary Interstitial Emphysema	48	25***	24	13***
Death from PAL	7	3	<1	1
Patent Ductus Arteriosus	66	57	54	45*
Necrotizing Enterocolitis	3	3	1	2
Pulmonary Hemorrhage	3	1	<1	1
Congenital Pneumonia	2	3	2	2
Nosocomial Pneumonia	5	7	2	2
Non-Pulmonary Infections	19	22	13	13
Sepsis	15	17	8	8
Death From Sepsis	<1	<1	1	<1
Meningitis	1	<1	1	<1*
Other Infections	5	8	5	6
Major Anomalies	3	3	4	4
Hypotension	62	57	50	39**
Hyperbilirubinemia	17	19	12	10
Exchange Transfusion	3	4	1	2
Thrombocytopenia[b]	10	11	4	<1**
Persistent Fetal Circulation	1	1	1	2**
Seizures	10	10	6	3*
Apnea	37	48	65**	37
Drug Therapy				
Antibiotics	100	99	98	98
Diuretics	60	65	45	34***
Anticonvulsants	17	17	10	5**
Inotropes	36	31	27	16***
Sedatives	72	68	76	64***
Pancuronium	34	17**	33	15***
Methylxanthines	62	74**	49	53

[a] All parameters were examined with "as-treated" analyses. * p<0.05
[b] Thrombocytopenia requiring platelet transfusion. ** p<0.01
*** p<0.001

Pulmonary Hemorrhage: See WARNINGS.

Abnormal Laboratory Values: Abnormal laboratory values are common in critically ill, mechanically ventilated, premature infants. A higher incidence of abnormal laboratory values in the Exosurf Neonatal group was not reported.

Events During Dosing: Data on events during dosing are available from more than 8800 infants in the open, uncontrolled clinical study (Table 5).

Table 5 — **Events During Dosing in the Open, Uncontrolled Study[a]**

Treatment Type: Number of Infants:	Prophylactic Treatment N=1127	Rescue Treatment N=7711
	% of Infants	% of Infants
Reflux of Exosurf	20	31
Drop in O_2 saturation (≥ 20%)	6	22
Rise in O_2 saturation (≥ 10%)	5	6
Drop in transcutaneous pO_2 (≥ 20 mm Hg)	1	8
Rise in transcutaneous pO_2 (≥ 20 mm Hg)	2	5
Drop in transcutaneous pCO_2 (≥ 20 mm Hg)	<1	1
Rise in transcutaneous pCO_2 (≥ 20 mm Hg)	1	3
Bradycardia (<60 beats/min)	1	3
Tachycardia (>200 beats/min)	<1	<1
Gagging	1	5
Mucous Plugs	<1	<1

[a] Infants may have experienced more than one event.
Investigators were prohibited from adjusting FiO_2 and/or ventilator settings during dosing unless significant clinical deterioration occurred.

Reflux: Reflux of Exosurf Neonatal into the endotracheal tube during dosing has been observed and may be associated with rapid drug administration. If reflux occurs, drug administration should be halted and, if necessary, peak inspiratory pressure on the ventilator should be increased by 4 to 5 cm H_2O until the endotracheal tube clears.

>20% Drop in Transcutaneous Oxygen Saturation: If transcutaneous oxygen saturation declines during dosing, drug administration should be halted and, if necessary, peak inspiratory pressure on the ventilator should be increased by 4 to 5 cm H_2O for 1 to 2 minutes. In addition, increases of FiO_2 may be required for 1 to 2 minutes.

Mucous Plugs: See WARNINGS.

OVERDOSAGE: There have been no reports of massive overdosage with Exosurf Neonatal.

DOSAGE AND ADMINISTRATION:

Preparation of Suspension: Exosurf Neonatal is best reconstituted immediately before use because it does not contain antibacterial preservatives. However, the reconstituted suspension is chemically and physically stable when stored at 2° to 30 °C (36° to 86 °F) for up to 12 hours following reconstitution.

Solutions containing buffers or preservatives should not be used for reconstitution. **Do Not Use Bacteriostatic Water for Injection, USP.** Each vial of Exosurf Neonatal should be reconstituted only with **8 mL** of the accompanying diluent (preservative-free Sterile Water for Injection) as follows: 1. Fill a 10 mL or 12 mL syringe with 8 mL preservative-free Sterile Water for Injection using an 18 or 19 gauge needle; 2. Allow the vacuum in the vial to draw the sterile water into the vial; 3. Aspirate as much as possible of the 8 mL out of the vial into the syringe (while maintaining the vacuum), then SLOWLY release the syringe plunger.

Step 3 should be repeated three or four times to assure adequate mixing of the vial contents. If vacuum is not present, the vial of Exosurf Neonatal should not be used.

The appropriate dosage volume for the entire dose (5 mL/kg) should then be drawn into the syringe from **below** the froth in the vial (again maintaining the vacuum). If the infant weighs less than 1600 grams, unused Exosurf Neonatal suspension will remain in the vial after the entire dose is drawn into the syringe. If the infant weighs more than 1600 grams, at least two vials will be required for each dose.

Reconstituted Exosurf Neonatal is a milky white suspension with a total volume of 8 mL per vial. Each mL of reconstituted Exosurf Neonatal contains 13.5 mg colfosceril palmitate, 1.5 mg cetyl alcohol, 1 mg tyloxapol, and sodium chloride to provide a 0.1 N concentration. If the suspension appears to separate, gently shake or swirl the vial to resuspend the preparation. The reconstituted product should be inspected visually for homogeneity immediately before administration. If persistent large flakes or particulates are present, the vial should not be used.

Dosage: Accurate determination of weight at birth is the key to accurate dosing.

Prophylactic Treatment: The first dose of Exosurf Neonatal should be administered as a single 5 mL/kg dose as soon as possible after birth. Second and third doses should be administered approximately 12 and 24 hours later to all infants who remain on mechanical ventilation at those times.

Rescue Treatment: Exosurf Neonatal should be administered in two 5 mL/kg doses. The initial dose should be administered as soon as possible after the diagnosis of RDS is confirmed. The second dose should be administered approximately 12 hours following the first dose, provided the infant remains on mechanical ventilation. A small number of infants with RDS have received more than two doses of Exosurf Neonatal as rescue treatment. Definitive data on the safety and efficacy of these additional doses are not available (see PRECAUTIONS).

Use of Special Endotracheal Tube Adapter: With each vial of Exosurf Neonatal Intratracheal Suspension, five different sized endotracheal tube adapters each with a special right angle Luer®-lock sideport are supplied. The adapters are chosen but not stenle. The adapters should be used as follows: 1. Select an adapter size which corresponds to the inside diameter of the endotracheal tube. 2. Insert the adapter into the endotracheal tube with a firm push-twist motion. 3. Connect the breathing circuit wye to the adapter. 4. Remove the cap from the sideport on the adapter. Attach the syringes containing drug to the sideport. 5. After completion of dosing, remove the syringe and RECAP THE SIDEPORT.

Administration: The infant should be suctioned prior to administration of Exosurf Neonatal.

Exosurf Neonatal suspension is administered via the sideport on the special endotracheal tube adapter **WITHOUT INTERRUPTING MECHANICAL VENTILATION.**

Each Exosurf Neonatal dose is administered in two 2.5 mL/kg half-doses. Each half-dose is instilled slowly over 1 to 2 minutes (30 to 50 mechanical breaths) in small bursts timed with inspiration. After the first 2.5 mL/kg half-dose is administered in the midline position, the infant's head and torso are turned 45° to the right for 30 seconds while mechanical ventilation is continued. After the infant is returned to the midline position, the second 2.5 mL/kg half-dose is given in an identical fashion over another 1 to 2 minutes. The infant's head and torso are then turned 45° to the left for 30 seconds while mechanical ventilation is continued, and the infant is then turned back to the midline position. These maneuvers allow gravity to assist in the distribution of Exosurf Neonatal in the lungs.

During dosing, heart rate, color, chest expansion, tidal expressions, the oximeter, and the endotracheal tube patency and position should be monitored. If heart rate slows, the infant becomes dusky or agitated, transcutaneous oxygen saturation falls more than 15%, or Exosurf Neonatal backs up in the endotracheal tube, dosing should be slowed or halted and, if necessary, the peak inspiratory pressure, ventilator rate, and/or FiO_2 turned up. On the other hand, rapid improvements in lung function may require immediate reductions in peak inspiratory pressure, ventilator rate, and/or FiO_2. (See WARNINGS and see below for additional information concerning administration.)

Suctioning should not be performed for two hours after Exosurf Neonatal is administered, except when dictated by clinical necessity.

General Guidelines for Administration: Administration of Exosurf Neonatal should not take precedence over clinical assessment and stabilization of critically ill infants.

Intubation: Prior to dosing with Exosurf Neonatal, it is important to ensure that the endotracheal tube tip is in the trachea and not in the esophagus or right or left mainstem bronchus. Brisk and symmetrical chest movement with each mechanical inspiration should be confirmed prior to dosing, as should equal breath sounds in the two axillae. In prophylactic treatment, dosing with Exosurf Neonatal need not be delayed for radiographic confirmation of the endotracheal tube tip position. In rescue treatment, bedside confirmation of endotracheal tube tip position is usually sufficient, if at least one chest radiograph subsequent to the last intubation confirmed proper position of the endotracheal tube tip. Some lung areas will remain undosed if the endotracheal tube tip is too low.

Monitoring: Continuous ECG and transcutaneous oxygen saturation monitoring during dosing are essential. In most infants treated prophylactically, it should be possible to initiate such monitoring prior to administration of the first dose of Exosurf Neonatal. For subsequent prophylactic and all rescue doses, arterial blood pressure monitoring during dosing is also highly desirable. After both prophylactic and rescue dosing, frequent arterial blood gas sampling is required to prevent post-dosing hyperoxia and hypocarbia (see WARNINGS).

Ventilatory Support During Dosing: The 5 mL/kg dosage volume may cause transient impairment of gas exchange by physical blockage of the airway, particularly in infants on low ventilator settings. As a result, infants may exhibit a drop in oxygen saturation during dosing, especially if they are on low ventilator settings prior to dosing. These transient effects are easily overcome by increasing peak inspiratory pressure on the ventilator by 4 to 5 cm H_2O for 1 to 2 minutes during dosing. FiO_2 can also be increased if necessary. In infants who are particularly fragile or reactive to external stimuli, increasing peak inspiratory pressure by 4 to 5 cm H_2O and/or FiO_2 20% just prior to dosing may minimize any transient deterioration in oxygenation. However, in virtually all cases it should be possible to return the infant to pre-dose settings within a very short time of dose completion.

Post-Dosing: At the end of dosing, position of the endotracheal tube should be confirmed by listening for equal breath sounds in the two axillae. Attention should be paid to chest expansion, color, transcutaneous saturation, and arterial blood gases. Some infants who receive Exosurf Neonatal and other surfactants respond with rapid improvements in pulmonary compliance, minute ventilation, and gas exchange (see WARNINGS). Constant bedside attention of an experienced clinician for at least 30 minutes after dosing is essential. Frequent blood gas sampling also is absolutely essential. Rapid changes in lung function require immediate changes in peak inspiratory pressure, ventilator rate, and/or FiO_2.

HOW SUPPLIED: Exosurf Neonatal for Intratracheal Suspension is supplied in a carton containing one 10 mL vial of Exosurf Neonatal for Intratracheal Suspension, one 10 mL vial of Sterile Water for Injection, and five endotracheal tube adapters (2.5, 3.0, 3.5, 4.0, and 4.5 mm). (NDC 0081-0207-01)

Store Exosurf Neonatal for Intratracheal Suspension at 15° to 30 °C (59° to 86 °F) in a dry place.

EDUCATIONAL MATERIAL: A videotape on dosing is available from your Burroughs Wellcome Co. representative. This videotape demonstrates techniques for safe administration of Exosurf Neonatal and should be viewed by health care professionals who will administer Exosurf Neonatal.

Licensed under U.S. Patent Nos. 4312860 and 4826821

BURROUGHS WELLCOME CO., Research Triangle Park, NC 27709
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Oxygen Enrichment of Expired Gas for Mouth-to-Mask Resuscitation

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BACKGROUND: One drawback to expired air ventilation for resuscitation is the relatively low oxygen concentration delivered (F_{DO_2}). METHOD & MATERIALS: We measured the F_{DO_2} provided to a bench model, during mouth-to-mouth and mouth-to-mask ventilation, without supplemental oxygen, by 12 volunteers skilled in Basic Life Support (BLS). The bench model consisted of resuscitation mannequin, trachea, and test lung with an oxygen analyzer, capnograph, and turbine spirometer incorporated into the tracheal portion. We then added an oxygen enrichment device (OED), and measured F_{DO_2} when oxygen was supplied to the device at flowrates of 5, 10, and 15 L/min. Participants were then instructed to inspire from the OED, the "inhalation technique," and F_{DO_2} was measured again at the three flowrates. RESULTS: The mean F_{DO_2} during expired air ventilation was 0.18. With supplemental oxygen at 5 L/min, mean F_{DO_2} increased to 0.29; with 10 L/min, to 0.36; and with 15 L/min, to 0.43. Using the inhalation technique, F_{DO_2} increased significantly ($p < 0.05$) compared to the standard technique. When the inhalation technique was used with oxygen at 5 L/min, mean F_{DO_2} rose to 0.36; with 10 L/min, to 0.57; and with 15 L/min, to 0.71. CONCLUSION: The use of supplemental oxygen during mouth-to-mask ventilation increases F_{DO_2}, and the use of the OED with the inhalation technique provides a higher F_{DO_2} than can be achieved with supplemental oxygen alone. The OED may be a useful device to achieve better oxygenation of victims during resuscitation. COMMENTARY: Mouth-to-mask ventilation offers distinct advantages to the BLS provider. Future design of mouth-to-mask devices should allow for oxygen enrichment and provide a filter as a barrier between patient and rescuer. (Respir Care 1991;36:99-103.)

Introduction

Many cardiac arrests occurring in the community are managed by first responders—firefighters, police, or emergency medical technicians—who must initiate resuscitation without the benefit of endotracheal intubation. The successful outcome of a resuscitative effort depends on the establishment of a patent airway and the institution of adequate ventilation.[1] First responders are often equipped with pocket masks and an oxygen supply. The techniques of mouth-to-mouth and mouth-to-mask ventilation continue to serve as important components of Basic Life Support (BLS) because they are effective, easily taught, and, perhaps, superior to other modes of noninvasive ventilation.[2] The use of mouth-to-mask ventilation is recommended in the American Heart Association Standards and Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care.[1] Further, the Centers for Disease Control suggests that a protective barrier that is effective against viral and bacterial contamination always be used between rescuer and patient during emergency ventilation procedures.[3]

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The views expressed in this article are those of the authors and do not reflect the official policy or position of the Air Force, Department of Defense, or U.S. Government. None of the authors has a financial interest in the reported products or the companies represented.

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Abbreviations Used in this Paper

BLS	— Basic Life Support
F_{DO_2}	— Fractional concentration of delivered O_2
OED	— Oxygen enrichment device
P_{etCO_2}	— End-tidal CO_2 tension
P_{IO_2}	— Inspired O_2 tension
V_T	— Tidal volume

One drawback of expired air ventilation is that it provides a relatively low delivered oxygen concentration (F_{DO_2}). We measured the F_{DO_2} that could be attained with mouth-to-mask ventilation incorporating various oxygen flows through the addition of an oxygen enrichment device (OED).* Additionally, we measured the maximal F_{DO_2} that could be achieved with the rescuer inspiring from the OED, prior to delivering a breath. We refer to this method of ventilation as the "inhalation technique."

Methods

For our study, the upper airway was modeled by the head of a standard Resusci-Anne. The neck outlet was connected to a test lung via a model trachea. A turbine spirometer, oxygen analyzer, and capnograph were interposed in the 'trachea' between the head and test lung (Fig. 1). Prior to use, the entire system was pressurized to 40 cm H_2O to assure that no leaks existed. The oxygen analyzer was calibrated with room air and 100% oxygen. A calibration syringe was used to test the spirometer, which we found to be accurate within ± 6% at flows consistent with the delivery of a 1-L tidal volume with a 1.5-second inspiration. Twelve volunteers (physicians, medical students, and respiratory therapists), trained in BLS, participated in the study. The volunteers were instructed to ventilate the model according to standard American Heart Association protocol (f = 12, V_T = 800 mL).[3] All volunteers were given 5 minutes to familiarize themselves with the model and the mouth-to-mask device and to practice the standard and inhalation techniques. We controlled for respiratory rate by counting aloud as if a second rescuer were performing cardiac compressions. The first two trials utilized mouth-to-mouth ventilation and then a mouth-to-mask device without supplemental oxygen. Following this, an OED was placed into the system above the one-way nonrebreathing valve (Fig. 2). The subjects repeated the trial with mouth-to-mask ventilation (inhaling from the room) with oxygen flowrates of 5, 10, and 15 L/min to the OED. The volunteers were then instructed to consciously inhale from the OED between ventilatory efforts, and the trial was repeated at oxygen flowrates of 5, 10, and 15 L/min. Each trial continued for 90 seconds or until F_{DO_2} was stable for a 30-second period. During each trial, F_{DO_2}, end-tidal carbon dioxide tension (P_{etCO_2}), and tidal volume (V_T) were

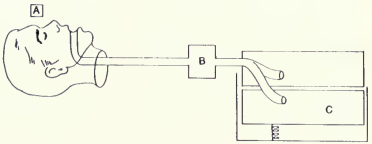

Fig. 1. Schematic representation of model designed to evaluate oxygen enrichment. A = Resusci-Anne head; B = interface for turbine spirometer, oxygen analyzer, and capnograph; C = test lung at compliance of 0.1 L/cm H_2O.

Fig. 2. Standard SealEasy Mask with one-way valve (left) and SealEasy Mask with oxygen enrichment device.

*Suppliers are identified in the Product Sources section at the end of the text.

continuously measured and recorded. Data were analyzed utilizing a standard statistical program, and the values were recorded as mean (standard deviation). Significance was determined via analysis of variance (ANOVA).

Results

F_{DO_2} ranged from 0.170 to 0.190 with mouth-to-mouth ventilation with exhaled air and from 0.169 to 0.192 with mouth-to-mask ventilation with exhaled air. The addition of the OED significantly increased F_{DO_2} at each level of flow ($p < 0.05$) (Fig. 3). The

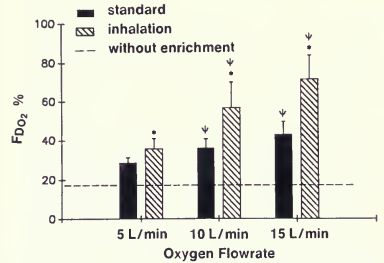

Fig. 3. F_{DO_2} values [mean (standard deviation)] obtained during expired gas ventilation via a mouth-to-mask device, with supplemental oxygen by standard and inhalation techniques. $\psi = p < 0.05$ vs previous flow-rate/same technique; * = $p < 0.05$ vs standard technique.

inhalation technique provided a statistically significant increase in F_{DO_2} when compared to standard techniques ($p < 0.05$). Delivered V_T increased as oxygen flowrate increased. This difference attained significance when standard technique at 15 L/min was compared to either mouth-to-mouth or mouth-to-mask technique using exhaled air ($p < 0.05$) (Table 1).

Discussion

Safar[4] first described the feasibility of oxygen enrichment during mouth-to-mask ventilation. He used the Laerdal pocket mask to achieve an F_{DO_2} of 0.54 during ventilation at a tidal volume of 1.0 L and a respiratory rate of 12 breaths/min. The results of our study are in agreement with those of Safar and, in addition, demonstrate significant additional oxygen enrichment through the use of the inhalation technique. The benefits of oxygen enrichment during cardiopulmonary resuscitation (CPR) are difficult to establish, but it is reasonable to suggest that resuscitative efforts should attempt to deliver the maximum oxygen concentration readily obtainable. Combining the inhalation technique with the use of an OED provides a significant increase in oxygen concentration during mouth-to-mask ventilation. The use of an OED and the inhalation technique are simple, easily taught, and could readily be incorporated into the existing BLS training programs.

The results of this study also demonstrate the adequacy of ventilation attained with the mouth-to-mask technique. The average V_T in this study was 1.38 L, which exceeds the 800-mL guideline established by the American Heart Association.[1] These results are similar to those of Hess et al[5] who found the SealEasy Mask and VentEasy non-rebreathing valve to be comparable to other currently available mouth-to-mask devices.

We observed that the addition of an OED resulted in augmentation of tidal volumes during standard mouth-to-mask ventilation. At an oxygen flowrate of 15 L/min, 250 mL/s of oxygen are delivered to the mouthpiece. If this flow is incorporated during a 1.5 second ventilation (AHA recommendation[1]), it would provide an additional 375 mL of delivered tidal volume. This may explain the significantly increased tidal volume that was observed during the standard technique trial at an oxygen flowrate of 15 L/min. This benefit was not observed during the inhalation trials and may reflect a smaller tidal volume as the rescuer attempts to limit inhalation to oxygen coming from the OED. P_{etCO_2} was monitored to ascertain that marked operator hyperventilation did not occur. For any specific P_{IO_2}, a reduced P_{etCO_2} from hyperventilation would increase F_{DO_2} simply because oxygen displaced CO_2. P_{etCO_2} did not change enough to account for the large changes in F_{DO_2} observed.

The use of a laboratory pneumotachograph would doubtless have yielded more precise and accurate measures of V_T. However, we believe that the reproducibility of the volumes measured by the hand-held spirometer (± 6%) is adequate to assure the credibility of our data. Accuracy actually increased with increasing oxygen concentrations (± 4% at

Table 1. Oxygen Concentrations and Tidal Volumes Delivered and End-Tidal Carbon Dioxide Partial Pressures Associated with Various Ventilator Techniques

Technique	F_{DO_2}	Tidal Volume (L)	End-tidal CO_2 (torr)
Mouth-to-mouth	0.180 ± 0.006*	1.38 ± 0.24	24.0 ± 3.0
Mouth-to-mask	0.182 ± 0.007	1.35 ± 0.32	21.3 ± 2.4
Mouth-to-mask - O_2 at 5 L/min	0.288 ± 0.025	1.43 ± 0.31	19.0 ± 1.8
Mouth-to-mask - O_2 at 10 L/min	0.362 ± 0.047	1.47 ± 0.38	17.1 ± 1.7
Mouth-to-mask - O_2 at 15 L/min	0.432 ± 0.065	1.51 ± 0.34†	16.8 ± 1.0
Inhalation mouth-to-mask O_2 at 5 L/min	0.359 ± 0.053	1.29 ± 0.25	20.8 ± 2.7
Inhalation mouth-to-mask O_2 at 10 L/min	0.569 ± 0.135	1.29 ± 0.31	18.6 ± 2.8
Inhalation mouth-to-mask O_2 at 15 L/min	0.715 ± 0.124	1.40 ± 0.22	17.8 ± 2.3

*Values are means ± standard deviation. Data was compiled and analyzed using ANOVA.

†$p < 0.05$ compared to mouth-to-mouth or mouth-to-mask.

100%). Our volume recordings do show a tendency for inspired volume to be approximately 5% less than expired volumes, which may be due to bidirectional flows in the system. However, the expiratory time was sufficient to allow the volume transducer to stop spinning prior to the next volume delivery. All volumes were measured in the same way.

Although the polarographic OM-11 oxygen analyzer does not respond as quickly as would a paramagnetic analyzer, we believe it to be adequate for the $\geq$ 90-second trials in this study. Also, we believe that any positive-pressure effects were dissipated during the stabilization period.

With today's concern for the transmission of communicable diseases, most notably acquired immunodeficiency syndrome (AIDS), rescuers may hesitate to perform mouth-to-mouth resuscitation. Other investigators have questioned the adequacy of bag-valve-mask ventilation in the nonintubated patient during one-rescuer BLS.[6-8] Mouth-to-mask ventilation is particularly advantageous for ventilatory support in the BLS setting. It offers the advantages of effectiveness, simplicity, ease of mastery, and the ability to provide a significantly enriched F_{DO_2}. However, we caution that, prior to use of the inhalation technique with the mouth-to-mask device, a filter be incorporated between the patient and the rescuer to eliminate possible transmission of infectious agents. The filter should be capable of eliminating viral and bacterial transmission without significantly altering the work of breathing or the flow characteristics of the device. This is particularly important in light of the findings of Hess and Kukula[9] that some nonrebreathing valves in mouth-to-mask devices allow a degree of backleak.

Use of the inhalation technique may also reduce oxygen supply requirements. The portable "D" oxygen tank, which at 2200 pounds per square inch gauge (psig) contains 350 L of oxygen, is often utilized by first responders. Ventilation techniques that utilize high oxygen flowrates ($>$ 15 L/min) will be limited to approximately 20 minutes use with one full tank. A potential advantage of the combination of inhalation technique with the OED is that it provides a $F_{DO_2} > 0.50$ at a flowrate of 10 L/min, thereby extending the life of a portable source.

Conclusion

Our results suggest that mouth-to-mask-ventilation provides a simple and effective means of providing prehospital ventilation. In addition, our results demonstrate that an F_{DO_2} of > 0.70 may be achieved utilizing mouth-to-mask ventilation with an OED and the inhalation technique. This method may also offer

the benefit of increased ventilation via augmentation of the rescuer's tidal volume.

PRODUCT SOURCES

Capnograph:
Hewlett-Packard Inc,
Palo Alto CA

Mask:
SealEasy, Respironics Inc, Monroeville PA

Model trachea:
Ima-trach, Mallinckrodt Critical Care Inc, Glengyle NY

Resuscitation mannequin:
Resusci-Anne, Laerdal Medical Corp, Armonk NY

Nonrebreathing valve:
VentEasy, Respironics Inc, Monroeville PA

Oxygen enrichment device:
OED, Respironics Inc, Monroeville PA

Oxygen analyzer:
OM-11, SensorMedics, Yorba Linda CA

Test lung:
TTL, Michigan Instruments, Grand Rapids MI

Turbine Spirometer:
Boehringer spirometer, Boehringer Laboratories,
Norristown PA

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Clinical Evaluation of ColdSpor, A Glutaraldehyde-Phenolic Disinfectant

Norman A Miner PhD and Carol Ross RRT

BACKGROUND: Disinfecting solutions may vary in concentration and bactericidal activity with use, may have subjectively unpleasant characteristics, and may affect the appearance and physical condition of the equipment processed. We evaluated the high-level disinfectant ColdSpor (0.5% glutaraldehyde, 0.025% ortho-phenylphenol, and 0.005% para-tertiary amylphenol) by using it as the disinfecting agent in the processing of equipment for a large respiratory care service. MATERIALS & METHOD: The type and quantity of equipment disinfected and the physical condition of the equipment were observed and recorded. Samples of the disinfectant solution were analyzed each week, and the antimicrobial activity of the solution was tested against clinical isolates and test cultures of *Pseudomonas aeruginosa*. The odor of the solution and ease of use were subjectively evaluated by two equipment-processing technicians. RESULTS: More than 2,400 pieces of respiratory equipment were passed through the disinfectant solution during the 30-day study period. No changes in the appearance of the equipment were noted. Analysis revealed that 71% or more of the antimicrobial chemicals remained in the solution. Clinical isolates and test cultures of *P aeruginosa* showed no growth when cultured with samples of the solution in use up to 30 days. The two technicians subjectively judged the solution to have no noticeable odor and to produce no burning of the eyes. CONCLUSION: The concentration of components of the glutaraldehyde-phenolic solution maintained bactericidal activity for as long as 30 days. The solution produced no apparent physical change in equipment and was subjectively acceptable to those processing equipment. (Respir Care 1991;36:104-109).

Background

Much respiratory therapy equipment is included in the category of semicritical equipment[1]—objects that come in contact with mucous membranes or skin that is not intact—and thus has the potential for being a source of hospital-acquired infections and should be subjected to high-level disinfection (ie, disinfection that can be expected to destroy all microorganisms except bacterial spores in large numbers).[2] The potential for respiratory care equipment (including bronchoscopes, biopsy forceps, cytology brushes, nebulizers, corrugated and smooth-bore tubing, heated humidifiers, IPPB masks, endotracheal tubes, and laryngoscopes) to be a source of hospital-acquired infections has been documented.[3,4] Clinicians have chosen many different ways to solve this problem, including using presterilized, disposable equipment and processing the equipment through high-level disinfectants. Solutions of 2% glutaraldehyde have gained acceptance as reliable, high-level disinfectants for

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heat-sensitive critical and semicritical medical equipment.[5] However, 2% and 3.2% glutaraldehyde may have drawbacks. First, depending on conditions of ventilation, container style, frequency of use, and staff sensitivity, the vapors of glutaraldehyde may be irritating or may cause allergic or even toxic reactions.[6] Second, Ascenzi, Ezzell, and Wendt[7] reported that various 2% glutaraldehyde disinfectants required more than 60 minutes at 20 °C to kill about 10^6 colony-forming units of *Mycobacterium bovis* BCG and questioned the ability of 2% glutaraldehyde to kill mycobacteria within practical conditions of exposure time and temperature. Respiratory care equipment can carry mycobacteria from one patient to another,[2,8] and Centers for Disease Control guidelines[9] require that all semicritical equipment be disinfected of virtually all non-spore-forming pathogens including mycobacteria. The disinfectant solution studied was formulated to address these two problems of 2% and 3.2% glutaraldehyde. The disinfectant's glutaraldehyde concentration is 0.5%, which is intended to reduce irritating vapors of the solution. Ortho-phenylphenol and para-tertiary amylphenol are included in the disinfectant because these phenolics are reported in the scientific literature to be odorless and highly tuberculocidal.[10,11] The objectives of this study were (1) to determine the concentrations of glutaraldehyde, ortho-phenylphenol, and para-tertiary amylphenol in the disinfectant at intervals up to 30 days of continuous clinical use, (2) to test the bactericidal activity of the disinfectant against clinical isolates and standard test cultures of *P aeruginosa*, (3) to note the subjective response of staff members to the odor of the disinfectant, and (4) to observe the effects of the disinfectant on the equipment processed.

Materials and Methods

Clinical Procedure

ColdSpor Lot No. 213916* was diluted 1:20 with tap water (in a plastic bucket), as directed by the label, to provide 12 gallons of solution. Respiratory care equipment was cleaned manually with detergent, rinsed with tap water, and placed in the 12 gallons of disinfectant solution. After a 30-minute soak, the equipment was removed, rinsed twice with tap water, and dried in a heated forced-air drying cabinet. The type and quantity of equipment were recorded in a log book from Monday through Friday each week. The odor of the disinfectant, rinsability, and physical condition of the equipment was subjectively evaluated and recorded daily. This procedure was continued for 30 days. Two gallons of fresh disinfectant diluted 1:20 with tap water were added on the 13th day to restore the total volume to about 12 gallons.

Chemical Analysis

At 3- to 4-day intervals, 100-mL samples of the disinfectant were collected from the 12-gallon container, placed in plastic containers, and stored at 20 °C for up to 45 days prior to chemical analysis. The concentration of glutaraldehyde was measured by reacting the glutaraldehyde with a known excess of sodium bisulfite and measuring the concentration of unreacted bisulfite by titration with triiodide as described by Frigerio and Shaw.[12] Concentrations of ortho-phenylphenol and para-tertiary amylphenol were measured by gas chromatography with a Hewlett-Packard 810 using an L-10 column. The pH of each sample was measured by an Orion 801 pH meter.

Antimicrobial Analysis

A typical patient isolate of *P aeruginosa* from Parkland Memorial Hospital was selected and cultured for 24 hours in trypticase soy broth. One mL of this *P aeruginosa* broth with $\geq 10^9$ cells/mL was added to 10-mL ColdSpor samples, mixed, and held for 10 minutes at 20 °C. Serial 10-fold dilutions were made into nutrient broth and observed for growth or no growth after incubation at 37 °C for 24, 48, and 96 hours. The disinfectant samples tested against *P aeruginosa* were collected after 30 days of continuous use.

P aeruginosa American Type Culture Collection (ATCC) #15442 was grown in nutrient broth for 48 hours, and tested against ColdSpor samples used for 30 days as described earlier.

*Suppliers are identified in the Product Sources section at the end of the text.

ColdTEST Minimum Effective Concentration Monitor

Approximately twice per week a 20-mL sample of disinfectant in clinical use was tested by the ColdTEST Minimum Effective Concentration (MEC) Monitor to determine whether the glutaraldehyde concentration exceeded 0.25%. The ColdTEST consists of adding 3 drops of phenolphthalein indicator to 20.0 mL of the disinfectant. The mixture of phenolphthalein and disinfectant is then drawn into a CHEMet glass vial containing sodium sulfite and sulfuric acid. If the concentration of glutaraldehyde in the solution is $\geq 0.25\%$, the glutaraldehyde reacts with the sodium sulfite to form enough base to overcome the sulfuric acid, thus producing a pH ≥ 8.3 at which the phenolphthalein indicator turns pink. At a glutaraldehyde concentration of $< 0.25\%$ the phenolphthalein in the CHEMet remains colorless.

Evaluation of Odor, Materials Compatibility, Rinsability, and Clarity

Technicians kept a daily written record of their subjective opinions of the odor of the disinfectant, condition of the respiratory care equipment before and after exposure to the disinfectant, number of rinses required to remove the disinfectant, and physical appearance (clear or cloudy) of the disinfectant.

Results

As shown in Table 1, a minimum of 2,429 pieces of respiratory care equipment were disinfected in the 14 total gallons of disinfectant during this 30-day evaluation. Technicians indicated no visible color or other noticeable change in the physical condition of the equipment. As subjectively recorded by the two technicians, two rinses in tap water removed all detectable traces of the disinfectant including glutaraldehyde odor and detergent sudsing. Some cloudiness became apparent in the disinfectant, but clarity was subjectively scored as "clear" or "good" throughout the 30 days. The written, subjective evaluations of two technicians of the odor of the disinfectant were "tolerable," "good," "odor is less noticeable (than previous 2% glutaraldehyde)," "odor is not noticeable," "no burning of the eyes," and "less coughing, sneezing, and burning of the eyes (than previous 2% glutaraldehyde)."

Table 1. Type, Quantity, and Condition of Equipment Disinfected in ColdSpor

Equipment Type	Total Pieces	Physical Condition after 30 Days
Aerosol tubing	992	No change; No color change; no damage
Nebulizers	701	Same as above
Heated humidifiers	142	Same as above
Smooth-bore tubing	452	Same as above
IPPB masks	30	Same as above
Bubble humidifiers	12	Same as above
Collection bottles	16	Same as above
Oxygen hoods	54	Same as above
Bacterial filters	12	Same as above
Siemens Servo ventilator components	18	Same as above
Total	2429	

Figure 1 shows the concentration of glutaraldehyde, ortho-phenylphenol, and para-tertiary amylphenol in ColdSpor Lot #213916 during 30 days of clinical use. The glutaraldehyde concentration dropped 28.6% from the second day to the thirtieth day of use. Ortho-phenylphenol concentration dropped 18%, and para-tertiary amylphenol dropped 12% during the 30 days of use. The pH of the disinfectant increased from 3.65 on Day 2 to 5.34 on Day 30. All samples of ColdSpor Lot No. 213916 as collected from the 30-day clinical study, and also fresh ColdSpor controls, were able to kill $\geq 10^9$ cells/mL of *P aeruginosa* as freshly isolated from a patient at Parkland Memorial Hospital or *P aeruginosa* ATCC #15442 within 10 minutes at 20 °C (Table 2). The disinfectant sampled from the plastic bucket during the clinical study was tested by the ColdTEST Minimum Effective Concentration

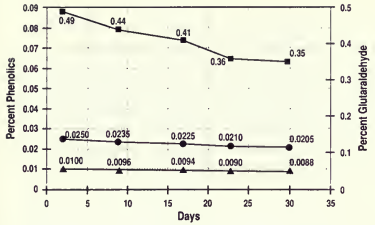

Fig. 1. The concentration of glutaraldehyde (■) and phenolics (ortho-phenylphenol [●] and para-tertiary amylphenol [▲]) in the disinfectant as a function of time in days of use.

Monitor on Days 2, 3, 6, 11, 13, 20, 23, 28, and 30, and all samples indicated that the glutaraldehyde concentration was ≥ 0.25%.

Discussion

Masferrer and Marquez[13] demonstrated that under clinical conditions disinfectants become inadvertently diluted during reuse as cycle after cycle of washed respiratory care equipment carries water into the disinfectant and then carries disinfectant to be rinsed away. This inadvertent dilution during reuse is a primary factor that affects how long a disinfectant may be used and reused under the reality of clinical conditions.

Table 2. Antimicrobial Activity of ColdSpor against a Clinical Isolate (C.I.) of *Pseudomonas* or *P aeruginosa* ATCC #15442 at Various Dilutions

Sample No.	ColdSpor Description	Pseudomonas Type	Growth (G) or No Growth (N) of a *Pseudomonas* Clinical Isolate (C.I.) or *P aeruginosa* ATCC #15442 at Various Dilution Factors								
			10^1	10^2	10^3	10^4	10^5	10^6	10^7	10^8	10^9
1	Fresh ColdSpor diluted 1:20 (0.5% glutaraldehyde)	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
2	Fresh ColdSpor diluted 1:100 (0.1% glutaraldehyde)	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N	N	
3	Clinical sample collected on Day 2	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
4	Clinical sample collected on Day 6	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
5	Clinical sample collected on Day 9	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
6	Clinical sample collected on Day 13	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
7	Clinical sample collected on Day 17	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
8	Clinical sample collected on Day 20	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
9	Clinical sample collected on Day 23	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
10	Clinical sample collected on Day 30	C.I.	N	N	N	N	N	N	N	N	N
		#15442	N	N	N	N	N	N	N		
11	Water only/negative control	C.I.	G	G	G	G	G	G	G	G	G
		#15442	G	G	G	G	G	G	G	G	N

Inactivation by organic soil (blood, mucus, tissue), evaporation, and chemical reactions (such as polymerization for alkaline glutaraldehyde) are other factors that also may limit the use life of a disinfectant.[14] Robison, Bodily, Robinson, and Christensen[15] compared the ability of several disinfectants to maintain antimicrobial effectiveness during use and reuse in the presence of added organic soil (blood) and under clinical conditions. In their study, one disinfectant labeled for use and reuse for 28 days lost its ability to kill *Salmonella choleraesuis* after 8 days of clinical use. It is therefore important to know how a disinfectant performs under clinical conditions, and the results may be very different from performance under laboratory conditions.

ColdSpor maintained 71.4% of its original glutaraldehyde concentration and 82% and 88%, respectively, of its original ortho-phenylphenol and para-tertiary amylphenol concentration during 30 days of use during which a minimum of 2,429 pieces of manually cleaned and washed respiratory care equipment was disinfected. The 2 gallons of fresh disinfectant solution (1:20) added to the solution in use on Day 13 to return the total volume to approximately 12 gallons would not increase the glutaraldehyde concentration in the total solution more than 0.1%. More glutaraldehyde was lost during the 30 days than ortho-phenylphenol or para-tertiary amylphenol, which may have been due to evaporation of glutaraldehyde or to glutaraldehyde polymerization as the pH rose to 5.34.

The minimum effective concentration for ColdSpor, defined as that minimum concentration that passes all Association of Official Analytical Chemists and Environmental Protection Agency tests supporting all label claims (bactericidal, pseudamonacidal, fungicidal, tuberculocidal, and virucidal) within 10 minutes at 20 °C, is 0.25% glutaraldehyde plus 0.015% improved phenolics.[16] That is, this disinfectant is formulated to withstand a 50% loss of its antimicrobial chemicals during clinical use. In this clinical study, the concentration of glutaraldehyde did not drop below 0.35%—well above the minimum effective concentration of 0.25%.

The measurement of odor was subjective. The written conclusions by the two equipment technicians suggest that the irritating odors sometimes experienced with 2% glutaraldehyde or phenol have been eliminated.

Each of the 8 tests with the ColdTEST monitor showed the disinfectant to have a glutaraldehyde concentration $\geq 0.25\%$. This ColdTEST result was in agreement with the chemical analysis.

Conclusions

The disinfectant solution (consisting initially of 0.5% glutaraldehyde with 0.025% ortho-phenylphenol and 0.005% para-tertiary amylphenol at a pH of about 5.0) maintained at least 70% of its initial antimicrobial chemical concentrations in this 30-day clinical test, maintained a pseudomonacidal chemical concentration, had a nonirritating odor, and was physically compatible with the equipment tested. Methodical application of a simple chemical test (ColdTEST) assured concentrations of components of $\geq 0.25\%$ glutaraldehyde, 0.0125% ortho-phenylphenol, and 0.0025% para-tertiary amylphenol.

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PRODUCT SOURCES

Disinfectant solution:
ColdSpor, Metrex Research Corp, Parker CO

Media:
Trypticase soy broth, Baltimore Biological Laboratories, Baltimore MD
Nutrient broth, Baltimore Biological Laboratories, Baltimore MD

Analytical equipment:
Gas chromatograph, Hewlett-Packard 810, Hewlett-Packard, San Jose CA
pH meter, Orion 801, Orion, Boston MA

Testing materials:
ColdTEST Minimum Effective Concentration (MEC) Monitor, CHEMetrics Inc, Calverton VA

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Is It Time for Universal Health Care in America?

Ron J Anderson MD

The time is rapidly approaching when we will have to decide how to rescue the sinking ship of health care in America. The safety net of our public hospitals is overflowing with patients from the 37 million uninsured Americans who have no other access to health care.[1] Furthermore, whether we recognize it or not, we all are headed for the same health-care lifeboat, and unless we ensure places for everyone, we will suffer individually and as a society.

The need for universal health care has been acknowledged by many groups. Several congressional commissions have studied the issue. The most recent, the Bi-Partisan Commission on Comprehensive Health Care—better known as the Pepper Commission—outlined an all-inclusive plan that would cover medical treatment, long-term care, and nursing-home care for all Americans. However, the Commission did not recommend a way to fund the estimated $66-70 billion cost.

A group called Physicians for a National Health Plan, the American College of Physicians, and other such bodies are on record as asking for a national health plan.[2] Recent surveys show that more than two thirds of Americans are dissatisfied with the cost and the access limits of the current system.[3]

In the absence of a new initiative, society's haves and have-nots are paying for a system that encourages the most expensive forms of resurrection medicine while containing costs by limiting health-care access to whole populations of people. In addition to paying for their own health care, the haves pay for the care of the poor *implicitly* through inflated hospital charges, spiraling insurance costs, and rising taxes. The have-nots pay *explicitly* for limited access with their health, their dignity, and even their lives.

The problems are hardly solved in existing programs for the poor, despite heroic efforts by some sectors. Many private nonprofit hospitals work with neighboring public hospitals and community health centers to form local networks of care for those who cannot pay. Nevertheless, demand almost always outstrips supply.

Although Medicaid was established as a state-operated program to finance health care to the poor, it covers only 24 million people—about half the total who need it. Two thirds of Medicaid's resources are consumed by the elderly and disabled, who comprise one third of Medicaid beneficiaries. The remainder are women and children who qualify as being poor.[4]

According to the Census Bureau, 75% of the 37 million individuals without health insurance are the working poor—either employed themselves or employed persons' dependents.[1] They don't receive health insurance through their employers, and they earn too much to qualify for Medicaid.

Because the reimbursement rate for services to Medicaid patients is notoriously low in many states, private physicians and hospitals often shun Medicaid recipients, not to mention the uninsured working poor. For example, studies done in the 1970s and 1980s show that 40% of obstetrician-gynecologists did not serve Medicaid patients.[5] As a result, these patients must go to the nearest public hospital, making a mockery of the *freedom-of-choice* concept promoted by physician lobbies.

Medicaid coverage and reimbursement vary by state, depending in part on each state's willingness to finance the options available through federal

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matching funds. Coverage ranges from penurious spending limits in some states to broad services and eligibility in others. Texas is among the worst states, covering only the poorest of the poor (approximately the lowest 20% of Texans live below the federal poverty level[6]). Medicaid reimburses my institution, Parkland Memorial Hospital in Dallas, for only about 45% of costs.

This inadequate and crazy-quilt approach not only delivers care to the poor haphazardly, but it unevenly distributes costs as well. Safety-net hospitals like Parkland respond to the bulk of health needs of the poor by providing uncompensated care. They additionally are being asked to serve as the health-care bulwark against infant mortality, teenage pregnancy, AIDS, crack cocaine, and violence-related injuries.

Nationally, the cost of unsponsored care (uncompensated care less appropriations from state and local governments) was $8.3 billion in 1988.[7] However, $2.2 billion of this cost was carried by only 57 of the nation's 6,780 hospitals.[8] These safety-net hospitals, therefore, comprise less than 1% of the nation's hospitals yet provide 27% of the uncompensated care, or an average of $38.5 million annually per hospital.

In Texas, approximately 80% of the uncompensated care is provided by seven of the state's largest urban public hospitals, including Parkland.[9] More than three million Texans live below the federal poverty line, which is an income of $12,675 for a family of four. They represent nearly 20% of the state's population; more than one third are children.[6]

In Dallas, approximately 350,000 residents live below the poverty level.[10] They are the primary users of Parkland, which serves as their family doctor and is the only public, tax-supported hospital in Dallas County. Approximately 70% of Parkland's patients qualify for charity care: More than 40,000 patients were admitted in 1989, and the outpatient clinics and emergency room handled a total of 582,700 patient visits.

Despite a neighborhood clinic system that provides prenatal care to 88% of the women who deliver at Parkland, a serious lack of prenatal care, particularly in the first and second trimesters, remains a major problem. Nearly 15,000 babies are delivered at Parkland each year, representing 42% of all births in Dallas County. Approximately 10% of the babies suffer low birthweights or are premature, requiring intensive care at a minimum cost of $1,500/day. Such problems are recurring themes at public hospitals across the nation, creating increasing health-care demands that serve as a negative barometer of the economy.

When the economy goes down, the demand for health care goes up, and public hospitals and public health-care systems take care of a disproportionate share of the indigent patients who have no other place to turn. It works until volume exceeds capacity; then quality of care is often sacrificed, along with the patient's dignity.

The strain on public hospitals' capacity is being exacerbated by the epidemics of AIDS, crack cocaine, and violence—and by the widespread prevalence of alcohol and drug abuse among pregnant women. Surveys of private and public hospitals say that at least 10-20% of pregnant women report using drugs or alcohol during their pregnancies.[11] The damage done by such abuse offsets gains made in improved prenatal care, to the point that we are losing ground in efforts to reduce low birthweight, infant morbidity (eg, congenital anomalies, learning disabilities, affective disorders, and withdrawal), and infant mortality.[12,13]

The heaviest burden of caring for indigent AIDS patients falls on the public sector. Of the nation's AIDS patients, 50% are treated in less than 5% of its hospitals, with the average revenue per patient visit being about 14% of the cost.[14] This pattern is also true for Parkland, which cares for approximately 60% of the AIDS patients in Dallas County. The nearly $10 million annual cost is largely unreimbursed.

Crack cocaine is the newest epidemic to strike our society, and it is remarkably associated with the spread of AIDS. Crack also is the primary factor in the rampant violence currently attacking major urban areas. Violent crime is at an all-time high in Dallas, where police reported a 24.7% increase in violent crimes for the first eight months of 1990, compared to the previous year.[15] The impact is reflected in the number of trauma cases treated at Parkland, which increased 30% in 1990.

With the surge in drug-induced violence, the associated need for trauma care is spilling over into those Dallas private hospitals that are voluntary members of the city's Emergency Medical System. These hospitals do not have to continue the

partnership and could withdraw their support. This has already happened in Houston, Los Angeles, Chicago, and Miami, where the lone public hospital in each community must deal with virtually all the city's trauma.[16]

But urban areas are far from alone in facing the difficulties of ensuring the availability of health care. The safety net of health care has all but disappeared in rural areas. Hospital closures and lack of obstetrical services are a problem in almost every state with a significant rural land mass and population.

In the decade of the 1980s, Texas led the nation in hospital closures, with 105 shut down; more than 60% of these were in rural areas. In 54 Texas counties there is no hospital at all; another 67 counties have only one hospital, which has less than 50 beds. Most of those remaining hospitals are not likely to survive through this decade. Of the state's 254 counties, 114 have no obstetrical services and offer only marginal pre-hospital care.[17]

Throughout the nation, doctors in small towns often cannot find dedicated and adequate transportation and inter-hospital care to transfer critically ill patients to urban hospitals capable of caring for them. They also encounter significant problems in getting urban hospitals to accept their non-paying patients. This is a critical health-care issue, considering that rural areas do not have the capability to handle trauma, neonatal intensive care, high-risk obstetrics, and other severe medical problems.

There is something desperately wrong in rural and urban areas alike. While millions of Americans do not have ready access to the system, some private hospitals are practicing boutique medicine, trying to earn a maximum profit while half their beds are empty.

This nation's health-care system is broken, because it is driven by utilization. American health insurance pays for the most expensive types of care and treatments, but it does almost nothing to encourage preventive medicine and health promotion. We can no longer afford this approach when hospitals cannot charge enough to cover their costs; when individuals as well as corporations cannot afford health-insurance premiums; and when insurance companies and the federal and state governments cannot and, I suspect, will not continue to finance fee-for-service, resurrection medicine in an open-ended, blank-check fashion. Already payer intermediaries second-guess nearly everything that providers do—in a manner as onerous as any government regulatory scheme. What's worse, despite the best efforts of the access-review firms, they still are not able to adequately control costs or ensure quality of care.

There Is a Better Way

We can create continuums of care that de-emphasize institutional care by addressing the well-being of patients. We need to create systems of health care that stress functionality as well as longevity in place of traditional medical-care systems, and we should fairly reward such new efforts. We are starting to do this for the underserved residents of Dallas through Parkland's Community Oriented Primary Care (COPC) program. The goal is to decongest the hospital's outpatient clinics and take health care into neighborhoods of high morbidity and mortality, where residents have not had access to primary-care services.

Parkland established COPC neighborhood health centers in 1989, and has already treated more than 90,000 patients. The centers focus on disease prevention and health education to reduce illness—and, consequently, to lessen future demand for costly secondary and tertiary care at Parkland. In 5 years, we hope to see 200,000 annual visits in such settings, at 60% of the cost of providing similar services at our 140-clinic, subspecialized facility at Parkland.

Preventive health measures work, as exemplified by prenatal care, which pays for itself many times over by reducing the need for neonatal intensive care. Indeed, the West Dallas pilot program that COPC is based upon decreased hospitalizations of children 75%, cut infant mortality 60%, and reduced teenage pregnancy 43% in less than a decade of operation. We also found that the cost of doing a better job is only a fraction of the previous cost, even before considering the contributions of improving the health status of a community and its members' productivity.

Parkland's experience shows that managed health care for indigent populations can be delivered efficiently and effectively through COPC programs. If funded by Medicaid on a larger scale, these programs would offer a vehicle that could allow sliding-scale purchase of primary medical care by the uninsured working poor.

The COPC model also could be easily adapted to rural areas. The program could create a lifeline

of care to underserved rural areas by linking them to referral networks with urban hospitals. Closed rural hospitals could be retooled and staffed to function as COPC health centers or Medical Assistance Facilities that render primary and emergency care and limited hospitalization before referring more critically ill or injured patients to urban hospitals via established networks.

Some system must be established before all existing capacity in rural communities dries up for good. To survive, the system must make good business sense for everyone involved, and it must create a win-win situation for both the urban and rural care providers.

One of the primary faults of our current system is that it isn't good business for our nation's economic vitality. That's why we are on the verge of a precipitous change in health care. As increasing numbers of American employers find that they cannot afford to buy health care for their employees, the overall health of the American worker will decline, resulting in our inability to compete in the world market. Additionally, the current high cost of health care is being passed on to purchasers of American products, thereby undermining our nation's competitive position in the global economy.

As a consequence of today's inadequate and costly health-care system, big business and big labor are calling for universal health care. Neither can afford to finance health care as it is practiced today, and they know that a healthy work force is essential to compete against countries whose infant mortality rates are a fraction of ours. Good public health creates healthier communities and a more productive work force.

It is through enlightened self-interest, then, that large corporations and unions already are concluding that universal health insurance is the way to address uncompensated care, control costs, and protect access. They are tired of shifting the costs. They want everyone to pay their share.

Workers who have health insurance as part of their benefits may have to pay more for elective coverage. If they want more than basic coverage, they should not be able to buy it with tax-exempt income as they currently do, unless as a society we are willing to provide similar coverage for citizens who require direct tax support.

Generous health-care benefits foster utilization, as does competition for the insured: The wealthier and healthier of our citizens. However, the overall cost could be minimized if we practiced medicine by emphasizing a universal program of health promotion, disease prevention, and public health.

We can always do better, and sometimes at lower cost. For example, we need better access to the value and contributions of new technology. We also need to assess more carefully the way we address certain clinical situations differently from location to location and from physician to physician; this could be done through better quality care reviews and through methodologies such as small-area analysis. All this should be done in the spirit of continuous quality improvement.

Costs most certainly would decrease if we were willing to recognize the interrelatedness of health care, education, economic opportunity, and decent housing. It is economically indefensible to continue to treat health problems related to poverty without also treating the root causes. By addressing the infrastructural issues of education, employment, and housing, society could transform many of its poor into taxpayers.

The fact that we have 37 million people without ready access to health care is an economic catastrophe for us all. We cannot become a more competitive country if we throw away whole populations of people. Neither can we enjoy internal tranquillity. Our most important resource is our population. In an information-driven, technological society, people will be either our greatest asset or a burgeoning albatross of homeless, unhealthy, uneducated, nonproductive citizenry.

This should plague our conscience as health-care professionals. Our concerted and individual efforts can make the difference in how communities and our nation address these problems. We must contribute to the debate and let our concerns and contributions serve as a lantern to guide those who make policy decisions.

Ethically, no matter what our station in life, we are of equal value. In the final analysis, we must recognize the universality of man in regard to disease and death and thus declare health care a basic right in this country. Once we make the ethical commitment and develop the political resolve, we will find the resources to provide universal, high quality, patient-valued health access for all our citizens.

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Baby, Why Are You So Tired?

Kari L Webber and Karla R Heim

A newborn girl, 34-weeks gestation, developed severe respiratory distress shortly after birth. She was transferred to a Level III neonatal center and received ventilatory assistance for 5 weeks. During this 5-week period, 20 chest tubes were inserted and an elective lung collapse was performed. Head ultrasound, hearing, and vision tests were performed prior to hospital discharge, and results were considered normal. However, her physicians anticipated that because of her extended hospital stay she might experience developmental delay.

Fig. 1. Anteroposterior (AP) chest radiograph of a 1-year-old girl experiencing undue fatigue.

The girl was in good health until 4 months of age, at which time she developed a 'bad cold.' Hospitalization was not required at this time, and no residual effects were noted. The mother noted that by 9 months of age the girl was becoming easily fatigued during normal activities.

At 1 year of age, the girl was admitted to a local hospital in severe respiratory distress. She was then

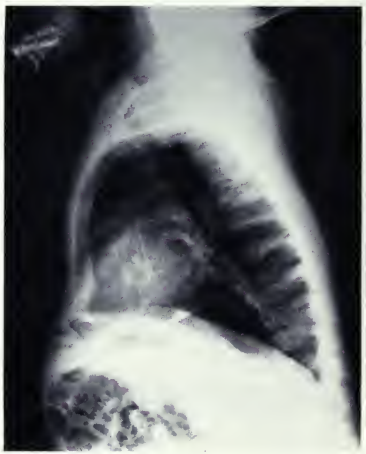

Fig. 2. Lateral chest radiograph of a 1-year-old girl experiencing undue fatigue.

Ms Webber is a staff respiratory therapist at St Olaf Hospital, Austin, Minnesota. Ms Heim is a staff respiratory therapist at the Mayo Clinic, Rochester, Minnesota. At the time this article was written, both authors were students enrolled in the Respiratory Therapy Program at Rochester Community College/Mayo Foundation, Rochester, Minnesota.

transferred to a larger medical facility where she was treated with albuterol and prednisone. After 2 weeks, her respiratory status was much improved; however, because of persisting fatigue and the potential for recurrence of respiratory symptoms, she was referred to an area medical center.

Upon examination at the medical center, the child was alert, happy, and assessed to be 7 to 8 months developmental age. She was acyanotic and breathing normally. Chest auscultation revealed normal breath sounds in the right hemithorax but diminished breath sounds in the left hemithorax. All laboratory data were normal. Admission anteroposterior (AP) and lateral radiographs are shown in Figures 1 and 2.

Questions

Radiographic Findings: What do the admission radiographs (Figs. 1 and 2) reveal?
Further Action: What therapeutic intervention is indicated for this child?

Answers and Discussion on Next Page

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Answers

Radiographic Findings: These radiographs reveal a hyperlucent left lung field and a mediastinal shift with possible compensation by the right lung. Likely causes of unilateral hyperlucency in a patient of this age include: a bulla; an air-filled cavity (pneumatocele); or central obstruction resulting from tumor, foreign body, or congenital bronchial defect. A diagnosis of pneumatocele was made in this patient on the basis of the chest radiographs in which a large, thin-walled, hyperinflated cavity is visible within the lung parenchyma.

Further Action: Because the radiographs indicated almost complete compression of the left lung by the pneumatocele, a fifth-interspace left thoracotomy was performed. A large, thin-walled pneumatocele was immediately evident, consuming approximately two thirds of the left hemithorax. It was densely adherent to the lung parenchyma and originated at the junction of the lingula and lower lobe. The left upper and lower lobes had collapsed and visualization of the lingula was impossible. Eighty percent of the pneumatocele was excised. Upon resection, the lung self-inflated, the lingula became visible, and the mediastinum returned to its normal position. The pathology report stated that the pneumatocele was suspected of having resulted from a nonspecific inflammatory reaction. Following surgery, the child made an uneventful recovery. A chest radiograph taken approximately 2 weeks after surgery is shown in Figure 3.

Fig. 3. Anteroposterior (AP) chest radiograph of a 1-year-old girl 2 weeks after surgical resection of a left-side pneumatocele.

Discussion

A pneumatocele, or pseudocyst, is defined as a hyperinflated cavity within the lung parenchyma. Fluid resulting from an inflammatory process may also be found in the cavity.[1] Pneumatoceles are thought to result from a check-valve type of airway obstruction.[2] Exudate, granulation tissue, or polyps may cause check-valve intraluminal obstruction. Trauma from airway suctioning has also been linked to the formation of check-valve obstruction. Pneumatoceles are often associated with childhood pneumonia caused by *Staphylococcus aureus,* which can elicit an intense inflammatory response resulting in tissue necrosis and destruction of alveolar walls.[3] Air can enter damaged alveoli, but has difficulty escaping. Pneumatoceles are an uncommon result of pulmonary interstitial emphysema (PIE). Those that tend to persist and enlarge are often those that occur later in the pathologic course.[4]

Most pneumatoceles resolve spontaneously. Those that persist or compromise respiration may require aggressive therapy. Surgical resection, successfully employed in this case, is one type of aggressive therapy. Selective endobronchial intubation is a second type of aggressive therapy and consists of passing a balloon-tipped catheter alongside the endotracheal tube and inflating the balloon within the bronchus of the affected lung. This prevents further enlargement of the pneumatocele. The partial pressure difference between gas in the pneumatocele and gas in the blood can lead to resorption of the air in 3 to 5 days. Complications associated with this therapy include difficulty in airway suctioning, infection, further pneumatocele enlargement resulting from balloon dislodgement, and balloon-induced pressure necrosis.[5]

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Cystic Fibrosis: A Guide for Patient and Family, by David M Orenstein MD. Softcover, illustrated, 239 pages. New York: Raven Press, 1989. $17.95.

The author, David M Orenstein MD, Director of the Cystic Fibrosis Center at the Children's Hospital of Pittsburgh, states that the goal of this book is to cover all the important topics that concern people with cystic fibrosis (CF) and their families. I think he achieves his goal.

The Introduction provides a simplified explanation of what CF is, which body parts are affected, and what causes CF. Here, as well as throughout the entire text, great effort is made to explain topics of concern in simple, easy-to-understand language. Most patients and family members possessing a high-school-level education in the biological sciences should have little difficulty comprehending the material presented. For example, when explaining how chest physical therapy removes secretions from the lung, the author uses the analogy of the ketchup bottle, which must be shaken and clapped to remove the thick substance.

Most respiratory care practitioners will be particularly interested in the first and longest chapter, which reviews the anatomy and function of the respiratory system, the effects of CF on the lungs, and the treatment of respiratory disease caused by CF. Subsequent discussion of respiratory care focuses on current methods of diagnosis and treatment for CF.

At the beginning of most chapters, the author explains how a particular topic of concern affects the normal human body; subsequently, he relates how the patient with CF is affected. This format is useful for providing clear explanations and practical advice. For instance, the chapter on exercise explains the responses of normal subjects and of CF subjects to exercise protocols. Both general and specific guidelines for establishing an exercise program are reviewed.

In current times, many CF patients reach adulthood and are faced with special difficulties. The chapter called "CF and Adulthood" addresses many patient concerns such as medical care, health insurance, education, employment, and marriage.

With new avenues of investigation flourishing as a result of the recent discovery of the gene that causes CF, the chapter about research is unfortunately dated. New potential treatments such as gene therapy and aerosolized amiloride (Midamor) are only hinted at by the author.

The book concludes with a review of the structure and function of the Cystic Fibrosis Foundation and a listing of nationally recognized CF centers and worldwide CF organizations. Again, as with the chapter on research, the listing is not completely current, and the practitioner is cautioned to contact the Cystic Fibrosis Foundation for the most up-to-date lists. Useful appendices provide a list of frequently prescribed medications, a glossary of terms, and an illustrated manual of chest physical therapy techniques.

In summary, this text is highly recommended not only as a valuable resource for patients and their families but as an excellent comprehensive guide for health care practitioners who routinely work with cystic fibrosis patients. Cystic Fibrosis Foundation Care Centers should consider obtaining this book as essential patient reference material.

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Readers Challenge Pressure-Controlled Inverse-Ratio Ventilation Editorial

Protocol for Implementation . . .

In response to the editorial entitled "Pressure-Controlled Inverse-Ratio Ventilation: Panacea or Auto-PEEP?"[1] by Dr Kacmarek and Mr Hess in the October 1990 issue of RESPIRATORY CARE, I would like to explain the policy that has been in effect in our hospital since we began using pressure-controlled inverse-ratio ventilation (PCIRV) 4 years ago. Prior to implementing PCIRV, we did search the literature, but none of the sources[2-5] we utilized are contained in the references cited by Hess and Kacmarek.

PCIRV is not initiated in our institution unless conventional ventilation including the use of high levels of positive end-expiratory pressure (PEEP) has failed to improve oxygenation. Before initiation of PCIRV, the patient is paralyzed and sedated and a Swan-Ganz catheter is placed. The equipment utilized includes a Servo 900C with Computer-Aided Ventilation Module, end-tidal CO_2 monitor, and pulse oximeter, and the health-care team (physicians, nurses, and respiratory therapists) are at the patient's bedside.

Baseline data include, but are not limited to, cardiac output, cardiac index, pulmonary vascular resistance, systemic vascular resistance, heart rate, blood pressure, static compliance, airway resistance, end-tidal CO_2, ineffective and effective tidal volumes, exhaled tidal volumes, pressure and flow waveforms, and arterial blood gas values. The ventilator settings are changed to pressure-controlled ventilation with inspiratory time of 50%. We continue to monitor the listed variables and modify ventilator settings as needed. At no time do we just switch the patient over to PCIRV and stop monitoring.

We have begun to look at the amounts of auto-PEEP, or inadvertent PEEP, generated by this type of ventilation and have found them to be about 7-10 cm H_2O—not over 20 cm H_2O.

Because the mortality rate in adult respiratory distress syndrome remains high, we must not summarily dismiss new advances in mechanical ventilation. I agree that PCIRV needs more study, but I also believe we should monitor these patients more closely. At the bedside, we have seen clinical improvement with this mode of ventilation.

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More on PCIRV . . .

Although I appreciate their concerns, I was astonished to read Dr Kacmarek and Mr Hess's editorial "Pressure-Controlled Inverse-Ratio Ventilation: Panacea or Auto-PEEP?"[1] Was their goal to call for further "scientific evidence to support the use of PCIRV," or was it to identify current users of this mode of ventilation as both uninformed and irresponsible for providing a mode of ventilation that ". . . is actually dangerous!"[1] In the 1990 edition of *Essentials of Respiratory Care,*[2] Kacmarek et al make no mention that PCIRV is either investigational or dangerous, indeed they do not caution against its use at all!

Kacmarek and Hess imply that the introduction of the Siemens Servo 900C is responsible for this "very uncomfortable and unnatural" form of mechanical ventilation. Although the manufacturers of the Servo 900C are not responsible for the development of PCIRV,[3] the ventilator does allow one to accurately and easily monitor auto-PEEP! In fact, the Siemens literature[4,5] plainly states that auto-PEEP exists, that it should be measured and monitored, and that it is the result of air trapping. This information has been readily available since 1987.[5] In our

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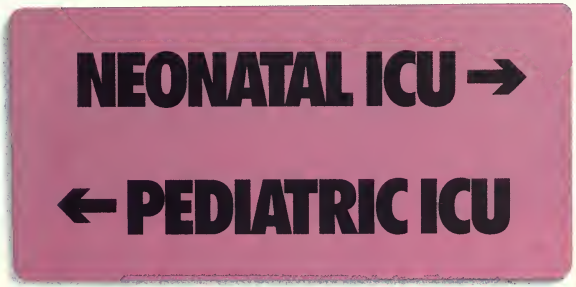

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institution when we use PCIRV, we simply record PEEP as "total PEEP" (applied PEEP + auto-PEEP).

Referring to reports by Tharratt et al[6] and Abraham et al,[7] the authors state "Perhaps most disturbing is that each of these papers advocating the use of PCIRV fails to acknowledge the short expiratory times produced by PCIRV resulted in the development of air trapping and auto-PEEP."[1] However reading those articles one finds Abraham et al stating "PCIRV is associated with auto-PEEP"[6] and Tharratt "one mechanism by which PCIRV is thought to exert its beneficial effect . . . is through increases in functional residual capacity"![7]

I do agree with Kacmarek and Hess that a "clinical scenario for mismanagement is created if auto-PEEP is not measured and documented."[1] Of course, that would be true of any mechanical ventilator setting. However, the tone of their editorial implies that therapists, other than themselves, are unable to properly monitor patients on PCIRV because "clinically important changes . . . can occur without being obvious to those caring for the patient."[1] Again, are they suggesting that those of us employing PCIRV are not competent enough to monitor hemodynamic changes relative to total PEEP and other mechanical and physiologic data in order to properly interpret our observations and take appropriate action? Perhaps we and they should be at least as concerned with the development of auto-PEEP on patients not on PCIRV![6]

From my experience and review of the literature, I am not convinced that anyone is touting PCIRV as a panacea for the treatment of ARDS. Even though patients must be selected carefully, and further research is definitely needed, I am convinced that PCIRV can and is being safely applied. Do we completely understand how PCIRV works—or for that matter do we completely understand how any mode of ventilation works? I don't think so. Despite having well over two decades of experience with PEEP, we're still learning how it works and how to use it.[9] Should the use of PEEP be considered investigational? If we apply the authors' logic, perhaps it should be.

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And Still More . . .

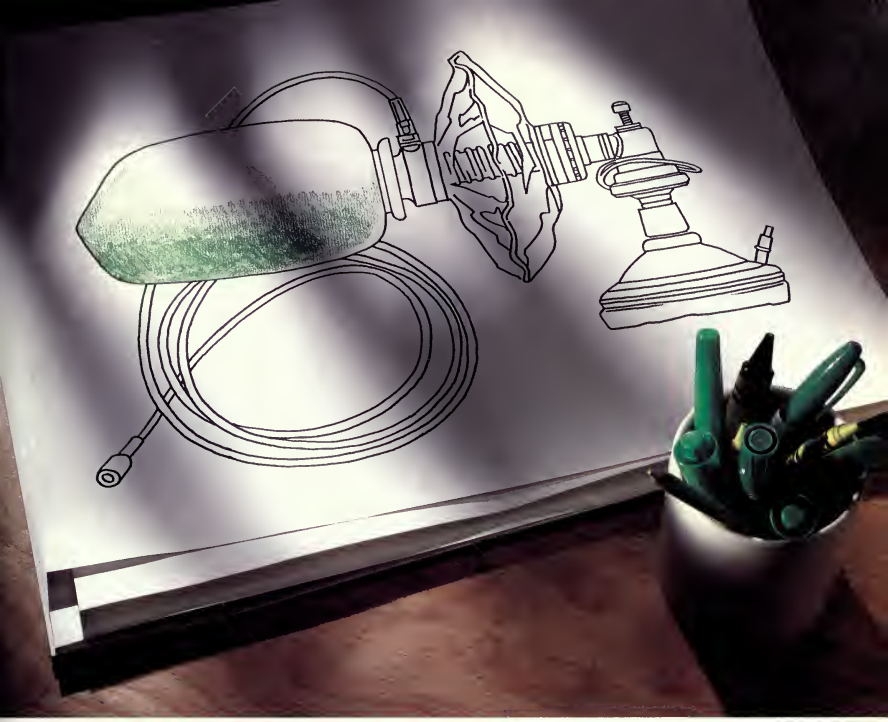
I read, with great interest, Dr Kacmarek and Mr Hess's editorial[1] discussing the use of pressure-controlled inverse-ratio ventilation (PCIRV) and auto-PEEP.

PCIRV has been advocated in the treatment of ARDS as Kacmarek and Hess indicate.[1,2] However, they seem concerned that the inverse ratio is unnatural and uncomfortable for the patient. This may be true. All forms of positive pressure mechanical ventilatory support are unnatural, and all can be more or less uncomfortable. Although, in many instances, sedation and paralysis are required during PCIRV, it is also not uncommon for sedation and paralysis to be necessary during conventional mechanical ventilation (CMV), particularly with high levels of positive end-expiratory pressure (PEEP).

Several reports[2-7] have suggested that PCIRV improves gas exchange at lower extrinsic PEEP levels. I believe this to be true and, further, it is important to note that peak inspiratory pressure (PIP) is also lowered.

Kacmarek and Hess suggest that some studies on the use of PCIRV are seriously flawed because of their retrospective design.[3,5] Granted, the gold standard in medical research is the well-controlled, prospective study. However, careful retrospective analysis of data holds an important place in medicine—or are all retrospective studies to be repudiated?

Auto-PEEP is of great concern to Kacmarek and Hess, as it should be. The majority of patients today are ventilated by conventional means. It is in these patients that the auto-PEEP phenomenon was first described.[8] Unrecognized auto-PEEP during CMV often causes major problems.[9] PCIRV clearly creates air trapping or a volume *e*ncumbered *e*xpiratory *p*ressure (*veep*, or auto-PEEP).[10] It is important in cases in which the auto-PEEP is being therapeutically applied to monitor the effects carefully. This can be accomplished by monitoring changes in P_{aO_2}, P_{aCO_2}, blood pressure, heart rate, cardiac output, and other systems that



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can be affected by an increase in intrathoracic gas volume. Kacmarek and Hess question whether increase in PEEP would have the same effect on oxygenation as PCIRV. In the studies they review, PCIRV was applied only after conventional ventilation using PEEP had failed to improve oxygenation.[3-7]

Bergman[11] in 1972 demonstrated that the volume of trapped air increased during CMV as he increased respiratory rate and tidal volumes in a group of seven men who were anesthetized and paralyzed. His work can easily be reproduced. What Kacmarek and Hess fail to acknowledge is Bergman's comment "Gas trapping, however, may not always be undesirable."[11]

Kacmarek and Hess seem exceedingly concerned about auto-PEEP during PCIRV. Auto-PEEP is purposely applied therapeutically by inverting the I-E ratio. PCIRV clearly encumbers a volume of gas in the lungs creating an end-expiratory pressure, increasing FRC and mean airway pressure, and improving oxygenation in many patients who are difficult to oxygenate with CMV and high levels of PEEP.[12] This is the desired effect of PCIRV. A greater concern to many clinicians is the hazard of hemodynamic compromise and other barotrauma from unrecognized auto-PEEP during CMV.[9]

Kacmarek and Hess do point out that PEEP in itself can have deleterious effects. I wholeheartedly agree with their suggestion that auto-PEEP be carefully monitored; and it should be monitored regardless of the mode of mechanical ventilation.

I believe that the measurement of auto-PEEP by a manual method may not be as easy or reliable as Kacmarek and Hess seem to suggest.[13,14] The 'hold' method suggested is uncomfortable for patients and difficult to synchronize within the total cycling time, particularly when repeated measurements are made.[10,13,14]

Tharratt et al[5] reported a 26% incidence of barotrauma when PCIRV was used. In a study by my colleagues and me,[3] no barotrauma was seen. PCIRV may be dangerous; mechanical ventilation may be dangerous. No one claims PCIRV to be a panacea—to do so would be absurd. However, to say that CMV plus PEEP will give equivalent results has not been proven. PCIRV will reduce the PIP.[2-6] CMV with PEEP will increase PIP levels. Kacmarek and Hess advocate using CMV with properly applied PEEP. However, there is no scientific evidence that PEEP improves the survival in ARDS patients, and the bulk of evidence suggests that high PIP exacerbates acute lung injury.[15-18] For that reason, many clinicians believe that decreasing PIP may be beneficial, not only in reducing barotrauma but also in reducing iatrogenic mechanically induced progression of acute lung injury.

Because no universally accepted guidelines for the proper application of CMV plus PEEP exist, the risk of misusing PEEP remains high.[19] But, as all clinicians are aware, careful and proper monitoring of all patients requiring mechanical ventilation is essential whether they are ventilated with CMV or with PCIRV.

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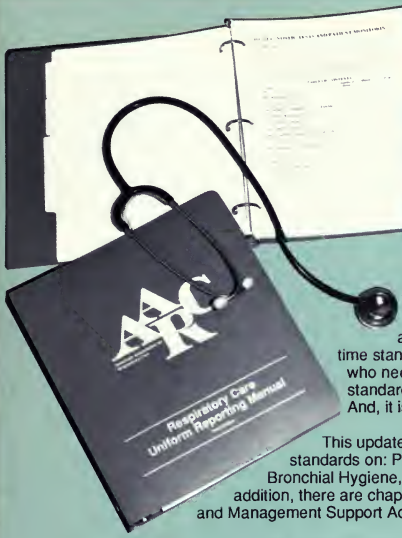

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More than Auto-PEEP?

In a recent editorial, Kacmarek and Hess[1] emphasized that the improved oxygenation observed during pressure-controlled inverse-ratio ventilation (PCIRV) may be due primarily to the underappreciated effect of auto-PEEP. Kacmarek and Hess properly criticize the enthusiasm for PCIRV when only flawed and retrospective studies have reported its effectiveness and few have investigated its mechanism of action.[2-4] However, in spite of the excellent points made in their editorial, there may be additional explanations, other than auto-PEEP alone, for the improvement in arterial oxygenation observed during PCIRV.

PCIRV may improve oxygenation by exposing alveoli to volume and pressure earlier in the respiratory cycle than does conventional, constant flow ventilation. Independently of auto-PEEP, the prolonged inspiratory exposure to pressure inherent in PCIRV also raises mean airway pressure (MAP)—a key determinant of arterial oxygenation.[5] The improvement may be due to recruitment of alveoli prone to remain unventilated at lower mean pressures or perhaps to collateral ventilation or better ventilation of units with long ventilatory time constants.[6-9] In support of this latter mechanism, PCIRV has been shown to reduce minute ventilation requirements,[3] whereas adding PEEP to conventional ventilation sufficient to raise MAP a similar amount often increases minute ventilation requirements.[10] Although auto-PEEP undoubtedly contributes to the improvement in oxygenation that occurs during IRV, improved oxygenation has been reported even when the level of end-expiratory alveolar pressure remained unchanged by ratio prolongation.[11]

PEEP prevents expiratory collapse of unstable alveolar units. When auto-PEEP is generated during IRV, it too should raise MAP while preventing end-expiratory alveolar collapse. However, significant gas trapping does not always occur during IRV. Characteristic of ARDS is a reduction in lung compliance that accelerates lung deflation during passive exhalation. Therefore, in the setting of ARDS, significant auto-PEEP is not as likely to occur until the inspiratory time is markedly extended. Assuming exponential deflation and a normally encountered level of expiratory resistance, usual ARDS conditions will not produce clinically important auto-PEEP until the I-E ratio exceeds 2:1 (Fig. 1).[12]

In summary, while the improved oxygenation frequently observed during IRV may be partially explained by auto-PEEP,[13] other mechanisms are also likely to be at work. With few of the above contentions well established, we hasten to agree with Kacmarek and Hess that until there is further investigation and clinical experience, IRV must be considered unproven and experimental, and it must be applied cautiously with full awareness of its potential benefits and hazards. We also agree that IRV requires meticulous monitoring of auto-PEEP, mean pressures, and the potentially varying minute ventilation.

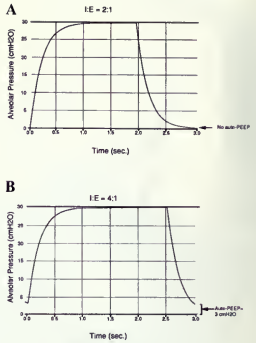

Fig. 1. Clinically important auto-PEEP is unlikely in ARDS until I:E > 2:1. Alveolar pressure tracings in ARDS with PCIRV at 2:1 (A) and 4:1 (B). Compliance = 0.02 L/cm H_2O, V_T = 0.6 L, f = 20, resistance = 10 cm H_2O/L/s, and set pressure = 30 cm H_2O.

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On a Monday night about 11:00 p.m., I took Nicholas to the emergency room at the local hospital. He had a hard time breathing. The emergency room doctor ordered the usual battery of tests including urine, blood, and chest X-ray. The X-ray showed signs of pneumonia. Nick's doctor suggested he spend the night in the hospital to see if he would stabilize.

Nick was placed in a normal pediatric ward. By morning Nick's condition deteriorated. My wife was with him all that day and she realized Nick would not survive on the course of therapy he was receiving. Nick was breathing at 120 breaths per minute and his lips and fingers were blue. My wife finally demanded that the nursing staff get in touch with our pediatrician. To make a long story short, Nick was transferred at midnight to the NICU at a major teaching hospital.

At the NICU, doctors started treating Nick more aggressively and continued giving Nick Virazole. By the next day, Nick's blood gases were much improved and we knew he had turned the corner and would make a successful recovery. Happily for all of us, Nick came home on the fifth day.

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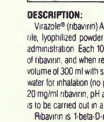

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CLINICAL PHARMACOLOGY:

Antiviral effects:

Ribavirin has antiviral inhibitory activity *in vitro* against respiratory syncytial virus,[1] influenza virus, and herpes simplex virus. Ribavirin is also active against respiratory syncytial virus (RSV) in experimentally infected cotton rats.[2]

In cell cultures, the inhibitory activity of ribavirin for RSV is selective. The mechanism of action is unknown. Reversal of the *in vitro* antiviral activity by guanosine or xanthosine suggests ribavirin may act as an analogue of these cellular metabolites.

Immunologic effects:

Neutralizing antibody responses to RSV were decreased in ribavirin treated compared to placebo treated infants.[3] The clinical significance of this observation is unknown. In rats, ribavirin resulted in lymphoid atrophy of thymus, spleen, and lymph nodes. Humoral immunity was reduced in guinea pigs and ferrets. Cellular immunity was also mildly depressed in animal studies.

Microbiology:

Several clinical isolates of RSV were evaluated for ribavirin susceptibility by plaque reduction in tissue culture. Plaques were reduced 85-98% by 16 µg/ml, however, plaque reduction varies with the test system. The clinical significance of these data is unknown.

Pharmacokinetics:

Assay for ribavirin in human materials is by a radioimmunoassay which detects ribavirin and at least one metabolite.

Ribavirin administered by aerosol is absorbed systemically. Four pediatric patients inhaling ribavirin aerosol administered by face mask for 2.5 hours each day for 3 days had plasma concentrations ranging from 0.44 to 1.55 µM, with a mean concentration of 0.76 µM. The plasma half-life was reported to be 9.5 hours. Three pediatric patients inhaling ribavirin aerosol administered by face mask or mist tent for 20 hours each day for 5 days had plasma concentrations ranging from 1.5 to 14.3 µM, with a mean concentration of 6.8 µM.

It is likely that the concentration of ribavirin in respiratory tract secretions is much higher than plasma concentrations in view of the route of administration.

The bioavailability of ribavirin aerosol is unknown and may depend on the mode of aerosol delivery. After aerosol treatment, peak plasma concentrations are less than the concentration that reduced RSV plaque formation in tissue culture by 85 to 98%. After aerosol treatment, respiratory tract secretions are likely to contain ribavirin in concentrations many fold higher than those required to reduce plaque formation. However, RSV is an intracellular virus and serum concentrations may better reflect intracellular concentrations in the respiratory tract than respiratory secretion concentrations.

In man, rats, and rhesus monkeys, accumulation of ribavirin and/or metabolites in the red blood cells has been noted, plateauing in red cells in man in about 4 days and gradually declining with an apparent half-life of 40 days. The extent of accumulation of ribavirin following inhalation therapy is not well defined.

INDICATIONS AND USAGE:

Ribavirin aerosol is indicated in the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus (RSV). In two placebo-controlled trials in infants hospitalized with RSV lower respiratory tract infection, ribavirin aerosol treatment had a therapeutic effect, as judged by the reduction by treatment day 3 of severity of clinical manifestations of disease.[3,4] Virus titers in respiratory secretions were also significantly reduced with ribavirin in one of these studies.[4]

Only severe RSV lower respiratory tract infection is to be treated with ribavirin aerosol. The vast majority of infants and children with RSV infection have no lower respiratory tract disease or have disease that is mild, self-limited, and does not require hospitalization or antiviral treatment. Many children with mild lower respiratory tract involvement will require shorter hospitalization than would be required for a full course of ribavirin aerosol (3 to 7 days) and should not be treated with the drug. Thus the decision to treat with ribavirin aerosol should be based on the severity of the RSV infection.

The presence of an underlying condition such as prematurity or cardiopulmonary disease may increase the severity of the infection and its risk to the patient. High risk infants and young children with these underlying conditions may benefit from ribavirin treatment, although efficacy has been evaluated in only a small number of such patients.

Ribavirin aerosol treatment must be accompanied by and does not replace standard supportive respiratory and fluid management for infants and children with severe respiratory tract infection.

Diagnosis:

RSV infection should be documented by a rapid diagnostic method such as demonstration of viral antigen in respiratory tract secretions by immunofluorescence[5] or ELISA[6] before or during the first 24 hours of treatment. Ribavirin aerosol is indicated only for lower respiratory tract infection due to RSV. Treatment may be initiated while awaiting rapid diagnostic test results. However, treatment should not be continued without documentation of RSV infection.

CONTRAINDICATIONS:

Ribavirin is contraindicated in women or girls who are or may become pregnant during exposure to the drug. Ribavirin may cause fetal harm and respiratory syncytial virus infection is self-limited in this population. Ribavirin is not completely cleared from human blood even four weeks after administration. Although there are no pertinent human data, ribavirin has been found to be teratogenic and/or embryolethal in nearly all species in which it has been tested. Teratogenicity was evident after a single oral dose of 2.5 mg/kg in the hamster and after daily oral doses of 10 mg/kg in the rat. Malformations of skull, palate, eye, jaw, skeleton, and gastrointestinal tract were noted in animal studies. Survival of fetuses and offspring was reduced. The drug causes embryolethality in the rabbit at daily oral dose levels as low as 1 mg/kg.

WARNINGS:

Ribavirin administered by aerosol produced cardiac lesions in mice and rats after 30 and 36 mg/kg, respectively, for 4 weeks, and after oral administration in monkeys at 120 and rats at 154 to 200 mg/kg for 1 to 6 months. Ribavirin aerosol administered to developing ferrets at 60 mg/kg for 10 or 30 days resulted in inflammatory and possible emphysematous changes in the lungs. Proliferative changes were seen at 131 mg/kg for 30 days. The significance of these findings to human administration is unknown.

Ribavirin lyophilized in 6 gram vials is intended for use as an aerosol only.

PRECAUTIONS:

General:

Patients with lower respiratory tract infection due to respiratory syncytial virus require optimum monitoring and attention to respiratory and fluid status.

Drug Interactions:

Interactions of ribavirin with other drugs such as digoxin, bronchodilators, other antiviral agents, antibiotics, or anti-metabolites has not been evaluated. Interference by ribavirin with laboratory tests has not been evaluated.

Carcinogenesis, mutagenesis, impairment of fertility:

Ribavirin induces cell transformation in an *in vitro* mammalian system (Balb/C3T3 cell line). However, *in vivo* carcinogenicity studies are incomplete. Results thus far, though inconclusive, suggest that chronic feeding of ribavirin to rats at dose levels in the range of 16-60 mg/kg body weight can induce benign mammary, pancreatic, pituitary and adrenal tumors.

Ribavirin is mutagenic to mammalian (L5178Y) cells in culture. Results of microbial mutagenicity assays and a dominant lethal assay (mouse) were negative.

Ribavirin causes testicular lesions (tubular atrophy) in adult rats at oral dose levels as low as 16 mg/kg/day (lower doses not tested), but fertility of ribavirin-treated animals (male or female) has not been adequately investigated.

Pregnancy:

Teratogenic Effects Pregnancy Category X See "Contraindications" section.

Nursing Mothers: Use of ribavirin aerosol in nursing mothers is not indicated because RSV infection is self-limited in this population. Ribavirin is toxic to lactating animals and their offspring. It is not known whether the drug is excreted in human milk.

ADVERSE REACTIONS:

Approximately 200 patients have been treated with ribavirin aerosol in controlled or uncontrolled clinical studies.

Pulmonary function significantly deteriorated during ribavirin aerosol treatment in six of six adults with chronic obstructive lung disease and in four of six asthmatic adults. Dyspnea and chest soreness were also reported in the latter group. Minor abnormalities in pulmonary function were also seen in healthy adult volunteers.

Several serious adverse events occurred in severely ill infants with life-threatening underlying diseases, many of whom required assisted ventilation. The role of ribavirin aerosol in these events is indeterminate. The following events were associated with ribavirin use.

Pulmonary: Worsening of respiratory status, bacterial pneumonia, pneumothorax, apnea, and ventilator dependence.

Cardiovascular: Cardiac arrest, hypotension, and digitalis toxicity.

There were 7 deaths during or shortly after treatment with ribavirin aerosol. No death was attributed to ribavirin aerosol by the investigators.

Some subjects requiring assisted ventilation have experienced serious difficulties, which may jeopardize adequate ventilation and gas exchange. Precipitation of drug within the ventilatory apparatus, including the endotracheal tube, has resulted in increased positive end expiratory pressure and increased positive inspiratory pressure. Accumulation of fluid in tubing ("rain out") has also been noted.

Although anemia has not been reported with use of the aerosol, it occurs frequently with oral and intravenous ribavirin, and most infants treated with the aerosol have not been evaluated 1 to 2 weeks post-treatment when anemia is likely to occur. Reticulocytosis has been reported with aerosol use.

Rash and conjunctivitis have been associated with the use of ribavirin aerosol.

Overdosage:

No overdosage with ribavirin by aerosol administration has been reported in the human. The LD_{50} in mice is 2 gm orally. Hypoactivity and gastrointestinal symptoms occurred in man. ribavirin is sequestered in red blood cells for weeks after dosing.

DOSAGE AND ADMINISTRATION

Before use, read thoroughly the Viratek Small Particle Aerosol Generator (SPAG) Model SPAG-2 Operator's Manual for small particle aerosol generator operating instructions.

Treatment was effective when instituted within the first 3 days of respiratory syncytial virus lower respiratory tract infection.[3] Treatment early in the course of severe lower respiratory tract infection may be necessary to achieve efficacy.

Treatment is carried out for 12-18 hours per day for at least 3 and no more than 7 days, and is part of a total treatment program. The aerosol is delivered to an infant oxygen hood from the SPAG-2 aerosol generator. Administration by face mask or oxygen tent may be necessary if a hood cannot be employed (see SPAG-2 manual). However, the volume of distribution and condensation area are larger in a tent and efficacy of this method of administering the drug has been evaluated in only a small number of patients. Ribavirin aerosol is not to be administered with any other aerosol generating device or together with other aerosolized medications. Ribavirin aerosol should not be used for patients requiring simultaneous assisted ventilation (see Boxed Warnings).

Virazole is supplied as 6 grams of lyophilized drug per 100 ml vial for aerosol administration only. By sterile technique, solubilize drug with sterile USP water for injection or inhalation in the 100 ml vial. Transfer to the clean, sterilized 500 ml widemouth Erlenmeyer flask (SPAG-2 Reservoir) and further dilute to a final volume of 300 ml with sterile USP water for injection or inhalation. The final concentration should be 20 mg/ml. **Important:** This water should not have had any antimicrobial agent or other substance added. The solution should be inspected visually for particulate matter and discoloration prior to administration. Solutions that have been placed in the SPAG-2 unit should be discarded at least every 24 hours and when the liquid level is low before adding newly reconstituted solution.

Using the recommended drug concentration of 20 mg/ml ribavirin as the starting solution in the drug reservoir of the SPAG unit, the average aerosol concentration for a 12 hour period would be 190 micrograms/liter (0.19 mg/l) of air.

HOW SUPPLIED:

Virazole® (ribavirin) Aerosol is supplied in 100 ml glass vials with 6 grams of sterile, lyophilized drug which is to be reconstituted with 300 ml sterile water for injection or sterile water for inhalation (no preservatives added) and administered only by a small particle aerosol generator (SPAG-2). Vials containing the lyophilized drug powder should be stored in a dry place at 15-25ºC (59-78ºF). Reconstituted solutions may be stored, under sterile conditions, at room temperature (20-30ºC, 68-86ºF) for 24 hours. Solutions which have been placed in the SPAG-2 unit should be discarded at least every 24 hours.

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Dr Kacmarek and Mr Hess respond:

An editorial is commonly written to present an opposing opinion, to clarify a position, or to bring a problem into focus. If the success of accomplishing this task can be judged by the controversy created and the dialogue established, then our editorial "Pressure-Controlled Inverse-Ratio Ventilation: Panacea or Auto-PEEP?"[1] has accomplished its goal. Above are four letters[2-5] written to the editor of RESPIRATORY CARE in response to this editorial; however, they represent only a small portion of the personal letters we have received and conversations we have had pertaining to this topic.

Ms McCabe,[2] Mr Cravens,[3] and Dr Lain[4] all argue that PCIRV can be safely administered by any practitioner in every setting, assuming that protocols outlined in the literature are followed. Both Ms McCabe and Mr Cravens indicate that the Siemens Servo 900C literature[6,7] provides guidance in the proper use of PCIRV. We agree that the Siemens literature is detailed and does caution on the development of auto-PEEP. However, in spite of the efforts of Siemens, the assumptions made in the application of PCIRV have not been established scientifically, and, as we have already indicated,[1] the majority of reports on PCIRV are anecdotal. No controlled study has established efficacy of PCIRV, nor has the methodology used to apply this modality been scientifically scrutinized.

We are not criticizing anecdotal reports and retrospective studies per se, as indicated by Dr Lain, but are simply trying to bring into focus their importance to medical science. In all aspects of clinical medicine, a pattern of implementation is normally followed for new techniques. Anecdotal reports raise the interest of the medical community in a specific treatment, and this stimulates systematic, controlled, prospective research designed to identify the efficacy of the treatment, document mechanism of action, and establish guidelines for its application. Only after this is completed should the therapy be applied universally.

It would appear that we in the field of respiratory care believe that the abandonment of the middle step, scientific scrutiny, is acceptable. We go directly from anecdotal reports to universal acceptance. We seem to be that rare medical specialty in which change in practice is primarily driven by industry. This is not to criticize industry because they do an exceptional job in educating practitioners. However, we do criticize the respiratory care community, because the community (including the authors) frequently do a poor job of scrutinizing new technology. Yes, there are examples of a less-than-scientific approach resulting in successful introduction of new practices (ie, pressure support); however, this approach has also resulted in dramatic and expensive failures (eg, IPPB).

To address the concerns of Mr Cravens, we do believe that unestablished and potentially dangerous approaches to patient management should be performed only at institutions capable of properly evaluating these techniques scientifically, and that usually means large medical center hospitals—not because of a lack of respiratory care expertise available at smaller institutions but because of a possible lack of other medical expertise.

Both Dr Lain and Mr Cravens indicate that no universal guidelines exist for the application of PEEP, with which we would also agree; however, there are *thousands* of studies that have evaluated the efficacy of PEEP and

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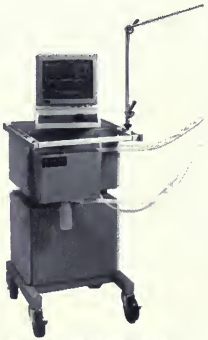

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defined its mechanisms of action. No such database is available to guide our use of PCIRV. As a result, as described by Ms McCabe, we establish elaborate approaches to monitor everything that may be affected adversely when PCIRV is used. We wonder, If practitioners were to be as attentive to conventional ventilation with PEEP, would their anecdotal reports be equally as promising?

Dr Lain argues that PCIRV improves gas exchange at lower PIP and extrinsic PEEP levels. This may be true, but no one has demonstrated that PCIRV results in lower total PEEP (extrinsic + auto-PEEP) levels. In fact, it is difficult, as we have indicated, to find reports that even list total PEEP levels. It is also argued by Dr Lain that air trapping and auto-PEEP are beneficial therapeutically.[4,8] However, this statement totally lacks substantiation. In fact, it can be argued that auto-PEEP and applied PEEP of the same level may have markedly different effects. The application of external PEEP results in a uniform establishment of the same end-expiratory pressure, regardless of the time constants (compliance × resistance) of individual lung units. This is not true of auto-PEEP. Auto-PEEP is established first in those lung units with the longest time constants, that is, with the greatest compliance or resistance.[9] As a result, those lung units most in need of PEEP for recruitment may not be affected by a given level of auto-PEEP. Because no lung disease is totally homogeneous, it is impossible to be assured that auto-PEEP has caused PEEP to be applied to those lung units with the shortest time constants. Additionally, because auto-PEEP may cause overdistention of lung units with the largest time constants, the incidence of barotrauma may actually be elevated because of unrecognized auto-PEEP.

Adams and Burke[5] argue that the beneficial effects of PCIRV may be explained by mechanisms other than auto-PEEP. They state that the pressure-flow waveform established during pressure-controlled ventilation exposes the alveoli to volume and pressure earlier in the respiratory cycle than does conventional, constant-flow ventilation. We agree, but do not believe the use of inverse I-E ratios or the establishment of auto-PEEP are necessary to demonstrate this potentially benefical effect of pressure control. In fact, the efficacy of pressure-controlled ventilation at I-E ratios of 1:2 has been recently demonstrated by Abraham and Yoshihara.[10] They noted a small increase in mean P_{aO_2} (from 80 to 92 torr) when 10 patients were changed from volume control to pressure control, with all other ventilatory variables kept constant. Although additional research is indicated, this systematic study does suggest that the use of pressure-controlled ventilation at normal I-E ratios may be beneficial.

Our primary concern with PCIRV is not the pressure-flow waveform, but the establishment of auto-PEEP. Inversing the I:E as a means of increasing total PEEP and mean airway pressure has many potential adverse effects, some of which are not easily recognized.[1] No one has demonstrated in a systematic manner (ideally, a prospective randomized, controlled study) the beneficial effects of inverse I-E ratios. Until such data are available, we continue to consider PCIRV experimental and caution against its use except in controlled clinical trials, and always encourage careful and constant monitoring if it is employed.

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Increased Airway Pressures in BEAR 2 and 3 Circuits following Airway-Pressure-Line Disconnection

Several therapists have reported to us that accidental disconnection of the airway pressure line (from the filter or the ventilator itself) of the patient circuit while a patient is being ventilated with either a BEAR 2 or BEAR 3 ventilator (Bear Medical Systems, Riverside CA) is signaled by both Low CPAP/PEEP and Low Pressure alarms and is associated with large increases in flow through the ventilator circuit.

We investigated these observations in an attempt to determine whether any ventilatory changes occurred at the patient connection during these episodes. In turn, we connected BEAR 2 and BEAR 3 ventilators to a TTL test lung (Michigan Instruments), with compliance = 0.3 L/cm H_2O, via a 7.0-mm endotracheal tube (ETT). We monitored pressures at the interface of the ventilator-circuit Y and the ETT (patient pressure) and compared them to the ventilator proximal pressures. We tested both ventilators at two tidal volumes (500 and 1000 mL) and two end-expiratory levels (5 and 10 cm H_2O). The disconnect was created by removing the airway pressure line from the ventilator. Tables 1 and 2 summarize our results.

We found that during a patient-ventilator disconnect in a situation where PEEP is being utilized, the BEAR 2 and BEAR 3 ventilators attempt to compensate for the loss of PEEP by increasing the flow into the circuit. This situation will cause a Low CPAP/PEEP and Low Pressure alarm, but in the process as much as 125 L/min will flow into the circuit. When the disconnect is the result of a leak that causes enough back pressure (eg, airway-pressure-line disconnect), pressure will be held in the circuit and baseline pressure will rise. The next mechanical breath will be delivered from this new baseline and will continue unless limited by the high-pressure limit. The operator may be unaware of any serious alterations in the airway pressure because the proximal airway pressure display reads zero. When the patient is not on any PEEP or when the leak is large, as occurs with disconnection of an inspiratory or expiratory line, the pressure will not increase.

Table 1. Pressures Measured during Ventilation by BEAR 2 with and without Airway-Pressure-Line Disconnection

V_T (mL)	Ventilator Proximal Pressure (cm H_2O)		Patient Pressure (cm H_2O)	
	Peak	PEEP	Peak	PEEP
500*	21	5	21	5
500†	0	0	54	20
500*	26	10	25	10
500†	0	0	54	20
1000*	36	5	25	5
1000†	0	0	64	21
1000*	42	10	40	10
1000†	0	0	64	20

*Measured in intact circuit.
†Measured with the airway-pressure line disconnected.

Table 2. Pressures Measured during Ventilation by BEAR 3 with and without Airway-Pressure-Line Disconnection

V_T (mL)	Ventilator Proximal Pressure (cm H_2O)		Patient Pressure (cm H_2O)	
	Peak	PEEP	Peak	PEEP
500*	22	5	21	5
500†	0	0	52	20
500*	28	10	26	10
500†	0	0	56	19
1000*	38	5	35	5
1000†	0	0	62	19
1000*	42	10	40	10
1000†	0	0	66	20

*Measured in intact ventilator circuit.
†Measured with the airway-pressure line disconnected.

We spoke with Mr AJ Beechko, Bear Medical product manager, about our observation. He confirmed our finding, but felt that the various alarms would alert the user to a possible problem. We do not believe that the operator's manuals[1,2] address this problem adequately. The manuals do mention the fact that alarms are triggered when the flow for PEEP compensation reaches 25 L/min, but nothing is said of the potential for

elevated pressures as the compensation progresses.

Our observations underscore the necessity for properly setting the high-pressure limit and for manually ventilating the ventilator-dependent patient when any alarm condition occurs, until the problem is properly diagnosed and corrected. Failure to do this may result in serious overinflation.

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2. BEAR 3 Adult Volume Ventilator instruction manual. 50000-10602. Riverside CA: Bear Medical Systems, 1989.

Mr Beechko responds for Bear Medical:

The work reported by Monaco and Goettel[1] points out the importance of a full evaluation of any ventilator alarm condition.

The specific issue addressed by Monaco and Goettel involves the response of the BEAR 1,® BEAR 2,® and BEAR 3® ventilators to a pressure sensing-line disconnection. The findings that they report reflect the fact that the three ventilators all incorporate a pneumatic system that receives feedback from the patient through this proximal pressure-sensing line. The monitored pressures allow the demand system to maintain a stable baseline pressure, even in the event of a leak, through the leak compensation system. An additional feature of the leak compensation system is that during a volume-assisted breath, an augmentation of flow and volume will occur if the patient demand for flow or volume is greater than the ventilator control setting. We estimate that this system has been applied clinically for more than 560 million hours and believe that it has benefited a large patient population.

In the untoward situation in which the proximal pressure-sensing line becomes disconnected, a leak may be generated that can result in a compensatory flow of up to 125 L/min. When this happens, the demand system no longer receives accurate feedback from the patient. Because such an event is possible during patient application, we have incorporated a series of alarms to detect the situation described by Monaco and Goettel. It is important for the readers of RESPIRATORY CARE to know that all alarms set on BEAR 1, BEAR 2, and BEAR 3 ventilators are activated from *machine pressure*. The importance of machine pressure monitoring is that the alarms are not dependent on the proximal pressure line. Therefore, in a disconnect situation the alarm package cannot be bypassed.

The Low Pressure Alarm is the first activated in the situation described by Monaco and Goettel. This alarm is activated when a positive pressure breath is delivered that is unable to transcend *machine pressure* above and below the threshold established by the alarm settingbut without an adequate initial fall and rise in pressure across the low-pressure threshold established by setting the alarm. Next, within 7-9 seconds of the commencement of compensatory flow of $>$ 22 L/min, the Loss of PEEP Alarm will activate due to the internal-flow-transducer monitoring system. This is discussed in our instruction manuals[2,3] in the Low PEEP/CPAP section. Additionally, the Low Tidal Volume Alarm will activate within 3 to 5 positive pressure breaths. The most important alarm to minimize risk under the situation described is the Pressure Limit Alarm. If the Pressure Limit Alarm is set at a clinically appropriate level above the observed peak pressure, then in a disconnect situation the peak pressure of a positive pressure breath will not exceed the pressure limit set. Again, the pressure limit alarm functions off of *machine pressure*, which is active even though the proximal pressure-sensing line has become disconnected. In the data presented by Monaco and Goettel, it is apparent that the pressure limit had been set well above what most clinicians may consider appropriate.

In summary, we encourage continual investigational work such as that conducted by Monaco and Goettel. Although this particular design technology has been functioning effectively for 17 years, we believe that updated reviews and recommendations are valuable to the respiratory care community. We agree with the authors' recommendations concerning proper utilization of all alarm settings. As the Warnings section of our instruction manual emphasizes, the need to investigate all alarm conditions is essential to the delivery of safe and effective mechanical ventilatory support.

A J Beechko
Product Marketing Manager
Bear Medical Systems Inc
Riverside, California

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2. BEAR 2 Adult Volume Ventilator instruction manual 50000-10530. Riverside CA: Bear Medical Systems, 1984.
3. BEAR 3 Adult Volume Ventilator instruction manual 50000-10602. Riverside CA: Bear Medical Systems 1989.

Does Indeed the Arterial-Alveolar Oxygen Tension Ratio Predict Successful Extubation? (Or—What the Abstract Did Not Tell)

From time to time, I believe, it is prudent that someone utter a cautionary word regarding conclusions drawn from published abstracts—and so I write this letter. By nature, an abstract is not a strong reference, and because of its format, it may not be fully revealing. Furthermore, not all published abstracts have passed peer review. Therefore, a conclusion drawn from an abstract, while it may be provocative or reassuring, should not be the basis for changing a policy, procedure, or behavior until the complete study results have been published and examined. I report here an example from my experience.

Recently, Lazar and colleagues argued in an abstract that an arterial-alveolar oxygen tension ratio (P_{aO_2}/P_{AO_2}) > 0.50 during T-piece weaning from mechanical ventilation "appears highly predictive of successful extubation."[1] In their prospective study of 78 patients, none of the 28 who had ratios > 0.50 required reintubation within 48 hours, whereas 7 of 50 (14%) with ratios < 0.50 did require such reintubation.

Because the therapists at our facility are responsible for extubation and intubation, after reading Lazar et al's abstract I anticipated that the use of this gas-exchange index, if indeed prophetic, would be most welcomed by the staff. To test Lazar et al's conclusion, I retrospectively reviewed 52 adult patients who had been mechanically ventilated in our 17-bed, mixed ICU for at least 48 hours, then weaned on a T-piece, and subsequently extubated after acceptable blood gas values had been attained.

I found that 34 patients had had ratios < 0.50 and that only two of them (6%) had required reintubation within 48 hours—which differed markedly from Lazar et al's 14%. Of our 18 patients with ratios > 0.50, three (17%) needed reintubation—in contrast to Lazar et al's 0%.

Why the differences? In an exchange of letters with Dr Lazar, he revealed that many of their patients "were extubated after 24 hours—eg, postop cardiac surgery." This crucial factor had not been stated in the abstract. The difference between our results could then be explained by the fact that Lazar et al studied essentially short-term patients, whereas my subjects were essentially pulmonary patients and had been mechanically ventilated at least 48 hours.

The P_{aO_2}/P_{AO_2} has been judged the most reliable of the oxygenation indices[2] and is highly functional in prediction formulas to determine the F_{IO_2} needed to attain a desired P_{aO_2}.[3,4] It has not been shown to be a sensitive and reliable indicator of intrapulmonary shunting.[5,6] I agree with Dr Lazar that a P_{aO_2}/P_{AO_2} ratio of < 0.50 does not preclude successful weaning, since the mean ratio of the successfully extubated patients in my < 0.50 group was 0.31. There is a strong suggestion that the short-term, nonpulmonary mechanically ventilated patient with $P_{aO_2}/P_{AO_2} > 0.50$ during T-piece weaning will not require reintubation within 48 hours.

Therapists and others must be wary of apparent realities in abstracts. In extrapolating from them, there is the danger of advocating procedures or policies based on information that, while 'true,' may be limited in scope because of the required brevity of the abstract form.

Edward Barber MA RRT
Clinical Resource
Respiratory Care
Salem Hospital
Salem, Massachusetts

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1. Lazar EJ, Heiman M, Lazar JM, et al. Does the a/A_{O_2} ratio predict successful extubation? (abstract). Chest 1990;98:74S.
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3. Maxwell C, Hess D, Shefet D. Use of the arterial/alveolar oxygen tension ratio to predict the inspired oxygen concentration needed for a desired arterial oxygen tension. Respir Care 1984;29:1135-1139.
4. Peris LV, Boix JH, Salom JV, Valentin V, Garcia D, Amau A. Clinical use of the arterial/alveolar oxygen tension ratio. Crit Care Med 1983; 11:888-891.
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☐ **Fetal Lung Development (VT23)** — By Charles Rosenfeld, MD. This tape examines the improved statistics on decreased perinatal and neonatal mortality over the last 15 years. The presentation then proceeds to fetal lung development in anatomical and biochemical phases. The four anatomical phases of fetal lung development are listed, described, and followed by an extensive discussion of the biochemical development of the fetal lung through gestation. This includes a description of the major substances in surfactant, the importance of their timely development, and its function is described along with the methods used to assess fetus survivability by using tracheal aspirant to identify the necessary ratios of the phospholipids making up surfactant. A question-and-answer session discusses methods to accelerate fetal lung maturation and current research on surfactant replacement therapy.

☐ **Pulmonary Rehabilitation (VT7)** — By John E. Hodgkin, MD. Dr. Hodgkin, active in developing a national framework for rehabilitative pulmonary medicine, provides an overview of the sequence for pulmonary rehabilitation. You will learn candidate evaluation and selection, rehabilitation team establishment, identification of short- and long-term goals, program components, assessment of patient progress, and long-term follow-up. Dr. Hodgkin then discusses contemporary thoughts on traditional respiratory therapy techniques, such as aerosol therapy, IPPB, oxygen therapy, and chest physiotherapy, used in treating COPD patients.

☐ **Drainage of the Pleural Space: Management of Chest Tubes and Bronchopleural Air Leak (VT21)** — By Martha L. Tyler, RRT, RN. With this tape you will learn the physiologic effects of abnormal pleural space function, e.g., pneumothorax, as well as one-, two-, and three-bottle chest drainage systems. Discussion covers the potential problems associated with chest tubes stripping, difficulties of bronchopleural air leaks with mechanical ventilation, the therapeutic goals of chest tube placement, and techniques for maintaining gas exchange with air leaks. Further discussion covers the operating characteristics and clinical efficiency of several commercially available chest drainage units.

☐ **Sleep Apnea (VT11)** — By Alan K. Pierce, MD. During the last decade, our understanding of the physiologic mechanisms and significance of ventilatory disorders during sleep has vastly improved. Dr. Pierce explains how sleep stages, as recorded by electroencephalography, are related to respiratory patterns and blood gas values in both normal and abnormal subjects. Includes a discussion of the criteria for defining the sleep apnea syndrome and the distinguishing features of central, obstructive, and mixed causes of apnea. Also addressed is the efficacy of medical treatment to correct specific types of sleep apnea.

☐ **Pulmonary Manifestations of AIDS (VT14)** — By Jon Weissler, MD. A historical perspective of Acquired Immune Deficiency Syndrome is presented, including epidemiological considerations, demographics, and social ramifications. Instruction is also provided on the pathogenesis of AIDS with emphasis on diagnosis and treatment of pulmonary manifestations. The lively question-and-answer session highlights precautions for health care workers concerning AIDS.

☐ **Practical Management of ARDS (VT16)** — By David Pierson, MD. Adult Respiratory Distress Syndrome is defined in this informative tape and its clinical features described, including incidence of risk factors and clinical predictors. Also extensively discussed is the use of PEEP to treat ARDS, including goals, complications, best or optional PEEP levels, PEEP trials, and PEEP withdrawal, as well as general treatment, prognosis, and sequelae of ARDS.

☐ **Modes of Conventional Ventilation (VT19)** — By Robert M. Kacmarek, PhD, RRT. A historical review of mechanical ventilation is presented, including the rationale for movement from one generation of ventilators to another. Ventilator modes discussed include control, assist/control (A/C), intermittent mandatory ventilation (IMV), synchronized intermittent mandatory ventilation (SIMV), mandatory minute ventilation (MMV), and pressure support ventilation (PSV). Description includes typical pressure wave forms of each mode.

☐ **Clinical Prediction and Prevention of ARDS (VT20)** — By Leonard D. Hudson, MD. The mortality of patients diagnosed with Adult Respiratory Distress Syndrome has remained unchanged since the term was first coined in 1976. This videotape investigates a system of dealing with potential ARDS patients, which may decrease mortality. The discussion centers on the identification of patients at risk of developing ARDS, their risk factors, and risk criteria. An approach to detect and prevent ARDS is presented.

☐ **Clinical Use of the Swan-Ganz Catheter (VT22)** — By John Marini, MD. Clinical applications of data obtained by Swan-Ganz catheter (SGC) placement and the situations in which SGC placement are useful are described in this video presentation. The clinical value of the clinical variables monitored by SGC and the complications of its placement are detailed, including "damping" of the waveform, "overwedging," and optimal lung zone placement.

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Calendar of Events

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AARC & AFFILIATES

February 28-March 3 in Anchorage, Alaska. The ASRC, the American Lung Association of Alaska, and the American Thoracic Society present their 19th Annual Meeting/Winter Conference at the Clarion Hotel in Anchorage. Contact Walter Hays at the American Lung Association of Alaska, (907) 276-5864.

April 3-5 in Baton Rouge, Louisiana. The LSRC presents the 21st Annual Educational Meeting and Exhibition, "Rx for Preservation of the Respiratory Care Profession," at Embassy Suites on I-10. Contact Jim Lanoha at (504) 381-6542.

March 22-23 in Lincoln, Nebraska. "Pulmonary Issues for the '90's," held at Southeast Community College, is sponsored in part by the NSRC. For more information contact Marcy Wyrens, Lincoln General Hospital, 2300 S 16th St, Lincoln NE 68502. (402) 473-5348.

March 10-13 in Denver, Colorado. The National Jewish Center for Immunology and Respiratory Medicine, in conjunction with the American Association for Respiratory Care and the American College of Chest Physicians, presents the 3rd International Conference on Pulmonary Rehabilitation and Home Mechanical Ventilation, with concurrent workshops on home ventilator care and pulmonary rehabilitation, at the Denver Hyatt. Contact Adele Gelfand, Conference Coordinator, (303) 398-1359.

April 10-12 in Bismarck, North Dakota. A New Decade of Strength in Respiratory Care is the theme for NDSRC's annual convention. Topics include nutrition studies, adult and neonatal critical care issues, and management strategies. For more information, call (701) 224-7870.

May 1-3 in Rapid City, South Dakota. Rapid City Regional Hospital hosts the annual convention of the SDSRC. Featured speakers (including WJ O'Donohue Jr MD, Robert Kacmarek PhD RRT, and Anthony Talbert MD) discuss neonatal, pediatric, and adult critical care issues. Contact Terry Anderson RRT, Respiratory Care Department, 1-800-232-9287.

May 28-31 in Jekyll Island, Georgia. The Georgia/South Carolina Region VI presents its 15th Annual Conference and Assembly at the Holiday Inn, Jekyll Island. Contact Mike Payne RRT, 730 South Pleasantburg Dr, Suite 525, Greenville SC 29607. (803) 879-0130.

OTHER MEETINGS

February 13-16 at Big Sky Resort, Montana. The American Lung Association of Montana sponsors the Big Sky Pulmonary/Ski Conference. Contact Earl W Thomas, Executive Director, American Lung Association of Montana, 825 Helena Ave, Helena MT 59601. (406) 442-6556.

March 7-8 in Madison, Wisconsin. The University of Wisconsin Medical School hosts the 6th Annual Comprehensive Management of Chronic Respiratory Problems Conference at the Sheraton Inn and Conference Center. Contact Cathy Means, Continuing Medical Education, 2715 Marshall Ct, Madison WI 53705. (608) 263-6637.

March 11-20 in Stanford, California. The Sleep Medicine and Technology Training and Education Center—Stanford holds one of many year-round courses with an emphasis on respiration during sleep. Selected audio tapes are also available. (415) 493-0131.

March 14-15 in Jacksonville, Florida. The American Lung Association of Florida's 4th Annual Pulmonary Critical Care Symposium. Contact Richard T Doggett, American Lung Association of Florida, PO Box 8127, Jacksonville FL 32239. 1-800-940-2933.

March 15 in New York, New York. The Joint Commission for the Accreditation of Health Care Organizations offers a Quality Assurance in Home Care seminar for providers and/or suppliers of home medical equipment, infusion therapy, and home health, personal care, and support services. Teachers are Joint Commission home-care surveyors with expertise in quality assurance. The seminar offers hands-on experience in quality assurance program development, implementation, and evaluation. Other seminars are scheduled for May 1 in Los Angeles, California; May 22 in Orlando, Florida; and September 27 in Princeton, New Jersey. For a brochure, contact the Joint Commission Customer Serivce Center at (708) 916-5800.

April 11-12 in Cape Cod, Massachusetts. The New England Association of Allied Health Educators holds its 8th Annual Meeting at the Hyannis Sheraton on picturesque Cape Cod. Conference program topics include Leadership and Communication and Designing Clinical Objectives. Contact Darcy Blitz or Julie Ann Mangini, South Central Community College, 60 Sargent Drive, New Haven CT 06511. (203) 789-6970.

May 12-15 in Anaheim, California. The American Lung Association and the American Thoracic Society host an International Conference in Anaheim. Contact Maureen J O'Donnell, Associate Director, Professional Development, American Lung Association, 1740 Broadway, New York NY 10019-4374.

August 25-September 1, Caribbean Cruise. Cruise the Western Caribbean aboard the SS Sea Breeze while earning 8 CRCE credits. Topic is "Aid for AIDS." $895 prepaid includes airfare, cruise, transfers, food, and entertainment. Friends and family welcome. Call or write Dream Cruises, 10882 LaDona Ave, Garden Grove CA 92640. 1-800-462-3628.

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1991 Call for Abstracts

The American Association for Respiratory Care and its science journal, RESPIRATORY CARE, invite submission of brief abstracts related to any aspect of cardiorespiratory care. The abstracts will be reviewed, and selected authors will be invited to present papers at the Open Forum during the AARC Annual Meeting in Atlanta, Georgia, December 7-10, 1991. Accepted abstracts will be published in the November 1991 issue of RESPIRATORY CARE. Membership in the AARC is not necessary for participation.

Specifications

An abstract may report (1) an **original study**, (2) the **evaluation of a method or device**, or (3) a **case or case series**. Topics may be aspects of adult acute care, continuing care/rehabilitation, perinatology/pediatrics, cardiopulmonary technology, health occupations education, or management of personnel and health-care delivery. The abstract may have been presented previously at a local or regional—but not national—meeting and should not have been published previously in a national journal.

The abstract will be the only evidence by which the reviewers will decide whether the author should be invited to present a paper at the Open Forum. Therefore, *the abstract must provide all important data, findings, and conclusions.* Give specific information. Do not write such general statements as "Results will be presented" or "Significance will be discussed."

Essential Content Elements

An **original study** abstract ***must*** include (1) Introduction: statement of research problem, question, or hypothesis; (2) Method: description of research design and conduct in sufficient detail to permit judgment of validity; (3) Results: statement of research findings with quantitative data and statistical analysis; (4) Conclusions: interpretation of the meaning of the results.

A **method/device evaluation** abstract ***must*** include (1) Introduction: identification of the method or device and its intended function; (2) Method: description of the evaluation in sufficient detail to permit judgment of its objectivity and validity; (3) Results: findings of the evaluation; (4) Experience: summary of the author's practical experience ***or*** a notation of lack of experience; (5) Conclusions: interpretation of the evaluation and experience. Cost comparisons should be included where possible and appropriate.

A **case report** abstract ***must*** report a case that is uncommon or of exceptional teaching/learning value and must include: (1) case summary and (2) significance of case. Content should reflect results of literature review. The author(s) should have been actively involved in the case and a case-managing physician must be a co-author or must approve the report.

Abstract Format and Typing Instructions

An optical scanner will be used to process abstracts. First line of abstract should be the title. Title should explain content. Type or electronically print the abstract ***double-spaced*** on ***plain white bond paper***, on ***one page*** only (copier bond is excellent). Do not underline or boldface and insert only one letter space between sentences. Provide a 1-inch margin top and bottom, a ½-inch left margin, and an approximate ½-inch ragged-right margin. Text may be submitted on diskette but must be accompanied by a hard copy.

No identification of authors or institutions is to appear on the abstract sheet or in the abstract itself. Make the abstract all one paragraph. Data may be submitted in table form ***provided the table width is limited to 60 letter spaces*** (ie, letters or numbers plus necessary blank spaces = 60). ***No*** figures or illustrations are to be attached to the abstract.

Type all information required to complete the author information form on the other side of this page. A photocopy of good quality may be used.

Standard abbreviations may be employed without explanation. A new or infrequently used abbreviation should be preceded by the spelled-out term the first time it is used. Any recurring phrase or expression may be abbreviated if it is first explained.

Check the abstract for (1) errors in spelling, grammar, facts and figures; (2) clarity of language; (3) conformance to these specifications. An abstract not prepared as requested may not be reviewed.

Questions about abstract preparation may be telephoned to the editorial staff of RESPIRATORY CARE at (214) 243-2272.

Deadlines

The mandatory Final Deadline is June 5 (postmark). Authors will be notified of acceptance or rejection ***by letter only***—to be mailed by August 15.

Authors may choose to submit abstracts early. Abstracts received by March 20 will be reviewed and the authors notified by April 26. Rejected abstracts will be accompanied by a written critique that should in many cases enable authors to revise their abstracts and resubmit them by the final deadline (June 5).

Mailing Instructions

Mail (Do not fax!) 1 copy of the abstract, 1 author information sheet, and a stamped, self-addressed postcard (for notice of receipt) to:

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Instructions for Authors and Typists

These Instructions are meant to guide authors and typists, including veterans in those roles, in the production of quality manuscripts. Perfection is not expected, but the well-prepared manuscript has the best chance for prompt review and early publication.

General Requirements

Submissions should (1) be related to respiratory care, (2) be planned for one of the publication categories below, and (3) be prepared as indicated in these Instructions. A letter accompanying the manuscript must specify the intended publication category, be signed by all the authors, and, when there are two or more authors, state that "We, the undersigned, have all participated in the work reported, read the accompanying manuscript, and approved its submission for publication."

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Research Article (Study): A report of an original investigation.
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Review of Book, Film, Tape, or Software: Anyone interested in writing a review can discuss it with an editor.

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Preparing the Manuscript

General Concerns—*Typist*

- Double-space ALL lines, including those in references, figure legends, and tables. Do not justify right margins.
- Number pages in upper right corner and leave margins of 1½" or more on all four sides of the page.
- For research articles, follow format of Model Manuscript, Respir Care 1984;29:182 (Feb 1984).
- Meticulously follow instructions for typing references.

General Concerns—*Author:*

- Structure manuscript as specified hereafter.
- Provide all requested information on title page as specified hereafter.
- Proofread manuscript for completeness, clarity, grammar, spelling; be sure all references, figures, and tables are cited in the text.
- Consider having paper reviewed in-house before submission.
- Have all co-authors proofread and approve manuscript and sign submission letter.

Manuscript Structure

Most kinds of papers have standard parts in a standard order. However, papers can vary individually, and not every paper will have all the parts listed here.

Research Article: Title page, abstract page, continuous text (Introduction, Materials & Methods, Results, Discussion), Product Sources page, Acknowledgments page, references, tables, figure legends. Please consult "Writing a Research Paper," Respir Care 1985;30:1057 (Dec 1985) and Model Manuscript, Respir Care 1984;29:182 (Feb 1984).
Evaluation of Device/Method/Technique: Title page, abstract page, continuous text (Introduction, Description of Device/Method/Technique, Methods of Evaluation, Results of Evaluation, Discussion), Product Sources page, Acknowledgments page, references, tables, figure legends.
Case Report or Case Series: Title page, abstract page, continuous text (Introduction, Case Summary, Discussion), Acknowledgments page, references, tables, figure legends. Also see "How To Write a Better Case Report," Respir Care 1982;27:29 (Jan 1982).
Review Article: Title page, Table of Contents page, continuous text (Introduction, History, Review of Literature, State of the Art, Discussion, Summary), references. May include figures & tables. No abstract. Table of Contents optional. Other formats may be appropriate.
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Abstract Page: Number this Page 1. List paper's title but omit authors' names. Abstract should be 200 words or less and must be informative, briefly specifying main points of paper, such as methods, results, and conclusions drawn.

Statistical Analysis: In research articles, identify statistical tests and chosen level of significance in the Methods section. In Results section, report actual P values.

Figures (illustrations): All photographs, diagrams, & graphs must be numbered as Figure 1, Figure 2, etc, according to the order in which each is first mentioned in the text. Photographs must be glossy prints 5 × 7 to 8 × 10 inches and should be black & white unless color is essential. Letters and numerals must be neat and large enough to remain legible if figure is reduced in size for publication. Final figures must be of professional quality, but 'rough' sketches may accompany the submitted manuscript, with final figures to be prepared after review. Identify each figure on back with a stick-on label showing figure number and arrow indicating top; omit author's name. Cover label with clear tape so ink will not smudge other prints. Supply three sets of unmounted figures. If figure has been published before, include copyright-holder's written permission to use it.

Figure Legends: List figure legends on a separate page, not on figures. If a figure has been published before, list the source in the legend.

Tables: Type each table on a separate page. Avoid more than 8 columns across. Continue a deep table on following pages. Give each table a number and descriptive title, placed above the table. Double-space ALL lines in tables, including column headings and footnotes.

Drugs: Brand names may be given, but always also show generic names.

Units of Measurement: In addition to conventional units of measure, show SI values and units in brackets after conventional expressions: ie, "PEEP, 10 cm H_2O [0.981 kPa]." For conversion to SI, see RESPIRATORY CARE 1988;33:861-873 (Oct 1988).

Commercial Products: If three or fewer commercial products are named in the text, list the manufacturer's name and location in parentheses the first time each is mentioned. If four or more products are named, do not list manufacturers in the text; instead, name the products and manufacturers in a Products Sources list at the end of the text. Provide model numbers when available.

Abbreviations: Use an abbreviation only if the term occurs several times in the paper. Write out the full term the first time it appears, followed by the abbreviation in parentheses. Thereafter, employ the abbreviation alone. Never use an abbreviation without defining it. Do not create new abbreviations unless absolutely necessary.

References:

- Use references to support statements of fact, indicate sources of information, or guide readers to further pertinent literature.
- Cite only published works—or works accepted for publication. When listing an accepted but still unpublished work, designate the accepting journal's name, followed by "(in press)."
- In the text, cite references by superscript numerals (half space above text), not in parentheses. The first reference cited in the text is number 1, the next is number 2, etc.
- In the reference list, place the cited works in numerical order.
- For the reference list, obtain author names, article and book titles, dates, volume and page numbers from the *original* cited articles and books, not from secondary sources such as other articles' reference lists, which often are inaccurate.
- Type references in medical-journal style. Examples appear at the end of these Instructions. Abbreviate journal names as in *Index Medicus*. A list of many journal-name abbreviations was published in Respir Care 1988;33:1050 (Nov 1988).
- DOUBLE-SPACE the lines of references.
- List ALL authors' names. Do not use "et al" to substitute for names.
- Identify abstracts, editorials, and letters as such. See examples.

Personal Communications, Unpublished Papers, and Unpublished Observations: List unpublished items in parentheses in the text, not in the reference list.

Examples of How To Type References

Notes: Although the examples here are printed with single-spaced lines, please double-space references in manuscripts. Also, note that words in article and book titles are not capitalized—except proper names.

Standard Journal Article:

1. Shepherd KE, Johnson DC. Bronchodilator testing: An analysis of paradoxical responses. Respir Care 1988;33:667-671.

Corporate Author Journal Article:

2. American Association for Respiratory Care. Criteria for establishing units for chronic ventilator-dependent patients in hospitals. Respir Care 1988;33:1044-1046.

Article in Journal Supplement:

(Journals differ in their methods of numbering and identifying supplements. Supply sufficient information to allow retrieval.)

3. Reynolds HY. Idiopathic interstitial pulmonary fibrosis. Chest 1986;89(3, suppl):139s-143s.

Abstract in Journal:

(Abstracts are not strong references; when possible, full papers should be cited. When cited, abstracts should be identified as such.)

4. Lippard DL, Myers TF, Kahn SE. Accuracy of pulse oximetry in severely hypoxic infants (abstract). Respir Care 1988;33:886.

Editorial in Journal:

5. Rochester DF. Does respiratory muscle rest relieve fatigue or incipent fatigue? (editorial). Am Rev Respir Dis 1988;138:516-517.

Letter in Journal:

6. Smith DE, Herd D, Gazzard BG. Reversible bronchoconstriction with nebulised pentamidine (letter). Lancet 1988;2:905.

Personal Author Book:

7. Nunn JF. Applied respiratory physiology. New York: Appleton-Century-Crofts, 1969.

Note: To specify pages cited in a book, place a colon after the year and then list the page(s). Examples: 1969:85 (one page), 1963:85-95 (series of contiguous pages), 1963:85,95 (separated pages).

Corporate Author Book:

8. American Medical Association Department of Drugs. AMA drug evaluations, 3rd ed. Littleton CO: Publishing Sciences Group, 1977.

Book with Editor, Compiler, or Chairman as 'Author':

9. Guenter CA, Welch MH, eds. Pulmonary medicine. Philadelphia: JB Lippincott, 1977.

Chapter in Book:

10. Pierce AK. Acute respiratory failure. In: Guenter CA, Welch MH, eds. Pulmonary medicine. Philadelphia: JB Lippincott, 1977:171-223.

Submitting the Manuscript

After preparing the manuscript according to these Instructions, perform a final proofreading and check for accuracy and completeness. Then mail three copies of the manuscript and three sets of figures to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229 (or Federal Express to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229). Manuscript copy on IBM-compatible or Macintosh disks in addition to the requisite three hard copies will facilitate processing (Macintosh preferred). Enclose a letter as specified under **General Requirements** at the beginning of these Instructions. Do not submit material that has been published or is being considered elsewhere.

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4. Are all pages double-spaced and numbered?
5. Are all references, figures, and tables cited in the text?
6. Are references typed in requested style?
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News releases about new products and services will be considered for publication in this section. There is no charge for these listings. Send descriptive release and glossy black and white photographs to RESPIRATORY CARE Journal, New Products and Services Dept, 11030 Ables Lane, Dallas TX 75229.

New Products & Services

LARYNGOSCOPE BLADE. According to the manufacturer, the 2001 Fiberlight laryngoscope blade offers the advantages of high power krypton light and the convenience of interchangeability with standard handles (the blade snaps easily to handles that have fittings manufactured to ISO 7376/1 standards). Mercury Medical, Dept RC, 11300-A 49th St N, Clearwater FL 34622. (800) 237-6418 or (813) 573-0088.

VENTILATOR-CIRCUIT SUPPORT SYSTEM. The Adjusaloc ventilator-circuit support system consists of a 3-joint adjustable, lockable ventilator arm and a variety of quick-release tubing attachments. According to the manufacturer, the Adjusaloc system is constructed of extremely strong but lightweight materials and can be adjusted for both height and angle; each joint is locked by a one-handed flick of a switch. The universal joint is designed to allow the restless patient to move beneath the circuit without the associated risk of extubation. The socket joint is designed to provide precise angular positioning of the connector. The Adjusaloc system can be mounted to either the ventilator or the bed frame. British-American Medical Inc, Dept RC, 26941 Cabot Rd, Suite 115, Laguna Hills CA 92653. (800) 866-1187.

SUCTION UNIT. The new Laerdal Compact Suction Unit with Disposable Collection System minimizes the time-consuming cleaning associated with the original model, which incorporated a reusable collection system. The collection bottle and tubing of the new system are discarded after use. According to the manufacturer, the unit is small (6.5 × 9 × 9 in), lightweight (under 5 lb), and provides vacuum levels to 550 torr and airflows of 30 L/min. The high-capacity disposable collection bottle is graduated and holds > 1200 mL of material. The bottle lid snaps firmly in place and features a built-in overflow protection device and a bacteria filter. Permanently attached caps are provided to seal the bottle contents prior to disposal. Disposable replacement bottle-and-tubing sets are available in packages of twelve. The bottle holder is adjustable to accommodate most other disposable bottle brands and styles. Laerdal Medical, Dept RC, One Labriola Court, Armonk NY 10504. (800) 431-1055.

OXYGEN REGULATORS. Puritan-Bennett has recently introduced a new line of oxygen therapy regulators, which includes: 4 standard preset regulator-flowmeter combinations, 4 standard adjustable diaphragm regulator-flowgauge combinations, 6 standard adjustable piston regulators, 2 new nonmagnetic adjustable regulators, 8 new Companion-360 preset regulators with flowmeters, and 2 new Companion-360 preset emergency regulators with auxiliary DISS outlets. Puritan Group, Dept RC, 10800 Pflumm Rd, Lenexa KS 66215. (800) 248-0890 (press 4) for home care or (800) 255-6773 for hospitals.

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C. ☐ Supervisor
D. ☐ Staff Technician
E. ☐ Staff Therapist
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